HumaStar 600

| User Manual

CE

Cat No. 16660/001

Human

Diagnostics Worldwide

REVISION LIST OF THE MANUAL

Rev. /DATE.	REVISION DESCRIPTION
01/2007-09	First edition
02/2007-11	Correction of typing errors
03/2008-03	New features of SW 1.7.1 implemented
04/2008-10	New features of SW 1.7.3 implemented (calibration status, reagent status, ISE module update)
05/2009-01	Typing errors corrected
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07/2011-06	Update for software 1.8.1 r2011.05.30
08/2011-09	Correction dimension

SYSTEM VERSION

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SERVICE UND SUPPORT

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1 SAFETY INSTRUCTIONS

1.1 Introduction

This manual is considered as a part of the instrument; it has to be at the operator's hand as well as at the maintenance operator's availability. For accurate installation, use and maintenance, please read the following instructions carefully. In order to avoid instrument damage or personal injury, carefully read the "GENERAL SAFETY WARNINGS", describing the suitable operating procedures. In case of breakdowns or any troubles with the instrument, apply to the local Technical Service.

1.2 User Warranty

HUMAN warrants that instruments sold by one of its authorised representatives shall be free of any defect in material or workmanship, provided that this warranty shall apply only to defects which become apparent within one year from the date of delivery of the new instrument to the purchaser.

The HUMAN representative shall replace or repair any defective item at no charge, except for transportation expenses to the point of repair.

This warranty excludes the HUMAN representative from liability to replace any item considered as expendable in the course of normal usage, e.g.: lamps, valves, syringes, glassware, fuses, diskettes, tubing etc.

The HUMAN representative shall be relieved of any liability under this warranty if the product is not used in accordance with the manufacturer's instructions, altered in any way not specified by HUMAN, not regularly maintained, used with equipment not approved by HUMAN or used for purposes for which it was not designed.

HUMAN shall be relieved of any obligation under this warranty, unless a completed installation / warranty registration form is received by HUMAN within 15 days of installation of this product.

This warranty does not apply to damages incurred in shipment of goods. Any damage so incurred shall be reported to the freight carrier for settlement or claim.

1.3 Intended Use of the Instrument IVD

The instrument is intended for in vitro diagnostic application by professional users. It has to be used for the expected purposes and in perfect technical conditions, by qualified personnel, in working conditions and maintenance operations as described in this manual, according to the GENERAL SAFETY WARNINGS. This manual contains instructions for professional qualified operators.

1.4 General Safety Warnings

Use only chemical reagents and accessories specified and supplied by HUMAN and/or mentioned in this manual. Place the product so that it has proper ventilation.

The instrument should be installed on a stationary flat working surface, free from vibrations.

Do not operate in area with excessive dust.

Work at room temperature and humidity, according to the specifications listed in this manual.

Do not operate this instrument with covers and panels removed.

Only use the power cord specified for this product, with the grounding conductor of the power cord connected to earth ground.

Use only the fuse type and rating specified by the manufacturer for this instrument, use of fuses with improper ratings may pose electrical and fire hazards.

To avoid fire or shock hazard, observe all ratings and markings on the instrument.

Do not power the instrument in potentially explosive environment or at risk of fire.

Prior to cleaning and/or maintaining the instrument, switch off the instrument and remove the power cord.

For cleaning use only materials specified in this manual, otherwise parts may become damaged. It is recommended always to wear protective apparel and eye protection while using this instrument. Respective warning symbols, if appearing in this manual, should be carefully considered.

1.5 Disposal Management Concept

The currently valid local regulations governing disposal must be observed. It is in the responsibility of the user to arrange proper disposal of the individual components.

All parts which may comprise potentially infectious materials have to be disinfected by suitable validated procedures (autoclaving, chemical treatment) prior to disposal. Applicable local regulations for disposal have to be carefully observed.

The instruments and electronic accessories (without batteries, power packs etc.) must be disposed off according to the regulations for the disposal of electronic components.

Batteries, power packs and similar power source have to be dismounted from electric/electronic parts and disposed off in accordance with applicable local regulations.

1.6 Instrument Disinfection

Analytical instruments for in vitro diagnostic involve the handling of human samples and controls which should be considered at least potentially infectious. Therefore every part and accessory of the respective instrument which may have come into contact with such samples must equally be considered as potentially infectious.

Before doing any servicing on the instrument it is very important to thoroughly disinfect all possibly contaminated parts. Before the instrument is removed from the laboratory for disposal or servicing, it must be decontaminated. Decontamination should be performed by authorised well-trained personnel only, observing all necessary safety precautions. Instruments to be returned have to be accompanied by a decontamination certificate completed by the responsible laboratory manager. If a decontamination certificate is not supplied, the returning laboratory will be responsible for charges resulting from non-acceptance of the instrument by the servicing centre, or from authority's interventions.

1.7 Biohazard warning

Analytical instruments for in vitro diagnostic application involve the handling of human samples and controls which should be considered at least potentially infectious. Therefore every part and accessory of the respective instrument which may have come into contact with such samples must equally be considered as potentially infectious.

For safety reasons, we have labeled instruments with the „BIOHAZARD“ warning label below.

FIGURE 1
Biological Hazard Symbol

Notes:

2 INTRODUCTION

The HumaStar 600 is a reliable in vitro diagnostic chemistry analyzer for automatic testing of routine clinical chemistry tests and electrolytes.

Being real random access, this HumaStar 600 is the ideal solution for medium to large size labs, with a throughput of more than 600 photometric tests/hour (720 tests/hour with ISE).

Continuous process can be achieved as samples sectors can be loaded quickly and simply allowing nonstop operation. Sectors can hold primary tubes and small sample cups.

Refrigerated reagent tray can hold up to 48 different containers ranging from 20 to 70ml depending on configuration.

The optional ISE unit gets electrochemical measurement of Na^+, K^+ and Cl^- electrolytes with automatic urine sample dilution. The instrument is controlled by a PC workstation that has graphical -user friendly- interface software. The software provides total control over the analyzing process and gives easy access to advanced statistical functions and reports. Versatile method setup comprises end point, fixed point, kinetics, ISE, coagulation, calculated and externals. Optional features include:

Flexible pre- and post washing for each test to prevent carryover.

Auto rerun with automatic dilution of samples which are out of linear range.

Automatically duplicate for result confirmation

Extra volume dispensing of water or reagent to improve accuracy.

Reagent integrity check for safe operation.

Automatic predilution for calibrators, controls, blanks and samples to fit any method insert.

Curve and linear calibration with unlimited number of standards for highest accuracy.

Other features include:

Onboard sample and reagent bar code reading assure positive identification.

Capacity sensor monitors sample and reagent volumes.

Instant mixing during dispense gives precise initial reaction time.

Automatic acceptance of calibrators, control and samples increase the walk away time.

- Current activity monitor screen indicates to the operator when the routine will be finished
- Clot detector
  - Low water consumption.

3 SYSTEM DESCRIPTION

3.1 Unpacking

Remove all the parts from their package.
When unpacking the instrument, please make sure that the following items are contained in the packing. In case of damage or missing item, please contact the supplier immediately.

Quantity	Description	REF
1	Software CD	16661
2	Reaction cuvettes (box of 1200)	16661/1
2	Drying block kit	16661/11
1	Reagent recipients with cap (x 30) vol. 70 ml	16661/2
1	Reagent recipients with cap (x 30) vol. 30 ml	16661/3
2	Peristaltic Pump tubing kit x 3	16661/4
2	Sample tubes 13 mm. kit x 100	16661/5
1	Halogen lamp 12V 20W	16661/7
5	Sample Rack	16661/15
1	Serial Cable	16661/16
1	User Manual	16660/001

TABLE 1

3.2 Installation

3.2.1 INSTALLATION REQUIREMENTS

Carefully read the safety instructions included in this manual.
Install the instrument on a hard floor with a resistance of at least 50 Kg/cm^2; use, if possible, ceramic or stone floor.
Avoid carpets or very soft rubber.
Mains should be close to the instrument (less than two meters) and must fulfill local regulations.
Free access to main switch is required. A distance of 50 cm from the left side of instrument to nearest table or wall is advisable. Right side must have a free space of at least 30 cm for ventilation purposes.
Space must be empty over instrument to 2.10 m. Avoid using shelves, walls or screens above instrument.
Instrument is mounted on wheels and can be moved towards the front for servicing and cleaning purposes. Allow free space of about two times the instrument depth.

! Instrument is Installation Category II. Instrument requires protective ground connection. Verify ground connection before installing the instrument.

! User must be warned about the use of instrument under abnormal grounding conditions. It is advisable not to complete installation under poor ground conditions.

3.2.2 ELECTRICAL CONNECTIONS

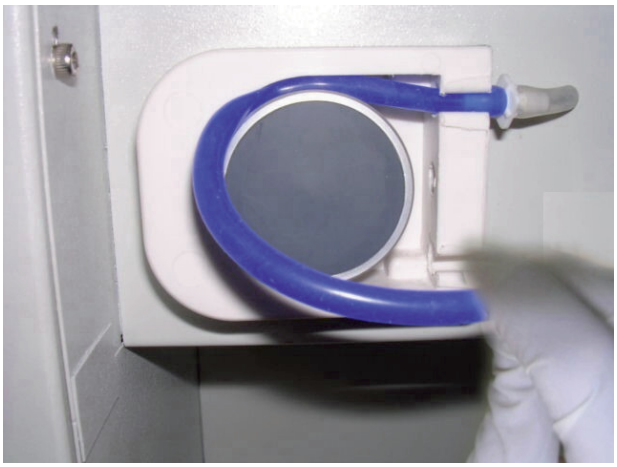
Plug in the mains cord to a socket with ground connection. The power requirements for the HumaStar 600 are as follows: **100~240 VAC, 50/60 Hz, 1000 VA** maximum.

Maximum voltage between ground and neutral lead: 0.5 volts.
There is a J9 serial port type RS232C connector in the rear part of the instrument (see Figure 1 2 oben). Connect the HumaStar 600 to the computer serial port using the provided cable. Tighten retaining screws.

3.2.3 HYDRAULICS

The waste deposit collects the drainage of the probe washing stations and occasional waste from the dispensing stations and cuvette washers. Place the emptied bottle in the correct location and orientation (see Figure 1 oben).
The washing solution is a dilution of 1 ml of additive (18981) per liter of DI water. Place the 10 L reservoir with washing solution and connect the yellow coded level sensor tubing on the corresponding fitting in the stopper. Do the proper with the two inlet transparent tubing for the washing solution.
Put the pump tubing of the washing pumps in place. Take out the plastic protection tube (typically yellow) from the probe arm‘s vertical shaft before operating.

FIGURE 2



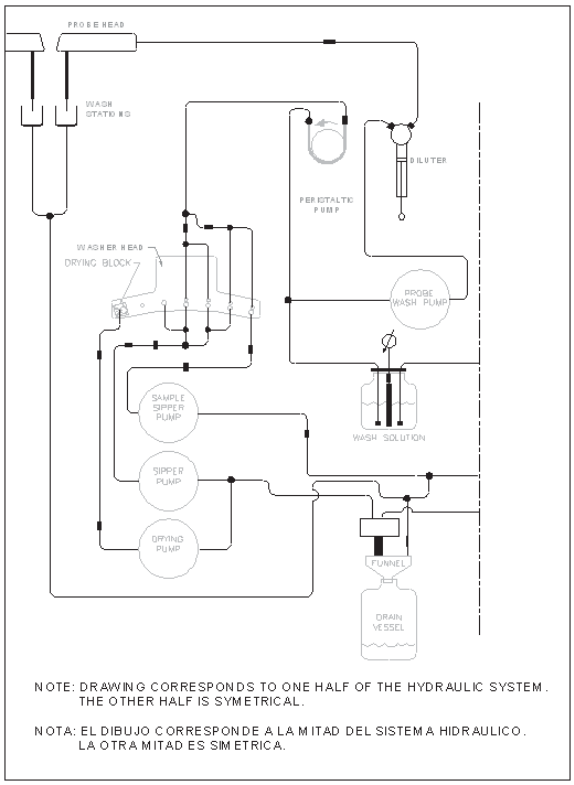


FIGURE 3

3.2.4 HANDLING OF BIOLOGICAL FLUIDS

Before connecting wash and drain lines, be sure to remember and understand regulations and cautions about potentially dangerous biological fluids.

Keep in mind the following considerations:

1. Due to the presence of biological fluids, some instrument areas are potentially dangerous. They are warned with the symbol

Dispensing tips, reaction cuvettes and drain fluid bottle are the most endangered areas.

! Never dispose potentially dangerous fluids on public drain system

1. Sample handling, drain fluid disposal and reaction cuvettes replacement must be done with safety disposable gloves manufactured according local regulations for biological fluids handling.
2. Drain fluid must be neutralized. The addition of 0,5 % Sodium Hypochlorite is suggested.
3. Verify and use local regulations on discarding pathological fluids.
4. If instrument is to be translated to other location or stored for a long period, perform at least 5 purge cycles, remove cleaning solution bottle and repeat purge cycles until drain lines are empty. Neutralize and dispose drain fluid.

3.2.5 COMPUTER SETUP

Follow the instruction set of the computer's manufacturer to connect and operate the computer system.

The minimum requirements for the computer are:

TABLE 2

Processor	3.0 GHz Intel Pentium 4
Memory	2 Gb DDRAM
Video adapter	64 Mb, AGP 2x
Monitor	17" (VIS 15.7")
Display resolution	1024x768 (vertical refresh > 70 Hz)
Colour quality	16 bits
Hard drive	80 Gb EIDE ATA-100 7200 rpm
CD-RW CD Read/Write	IDE 48/16/48 Speed
USB port	1.1 or 2.0
Keyboard	105-key Performance keyboard
Pointing device	PS2 or USB mouse
Soundcard	Integrated 16 bit (optional)
Speakers	(optional)
Network adapter	Ethernet 10/100 Mbits
Serial Port	RS-232 serial port
Operating system	MS-Windows XP or MS-Windows Vista.

Compatible printer

Any Windows™ compatible printer maybe installed .

LIS must be installed in a different computer connected through serial port.

The visual effects to best performance.

Change the setting of the operating system. Under properties →Advanced options → visual effects select "Adjust for best performance"

Setting of the Anti Virus Software
We recommend the use of Anti Virus Software on the Personal Computer of the HumaStar 600. The HumaStar 600 "Rayo" directory has to be excluded from the scanning process. Please refer to the documentation of the Anti Virus Software
Don't use the predefined MS Windows XP and VISTA folders.

As a default setting MS Windows is using predefined folders. This user profiles are located in Windows XP (C:\Documents and Settings) and in VISTA (C:\users). This includes "My documents", "Desktop", "Favorites", "My Music" etc. Big files will reduce the computer performance.
Don't use predefined directories to store data. Move all files to other directories (e.g. C:\documents).
The PC shall be used only for the operation of the instrument.
Any other programms besides the instrument software may cause instrument malfunction and/or breakdown.

3.2.6 PARAMETERS

There are few parameters for software and instrument use accessible to operator. They are located in

3.2.6.1 Software

Includes pages for communications, LIS and bar code reader.

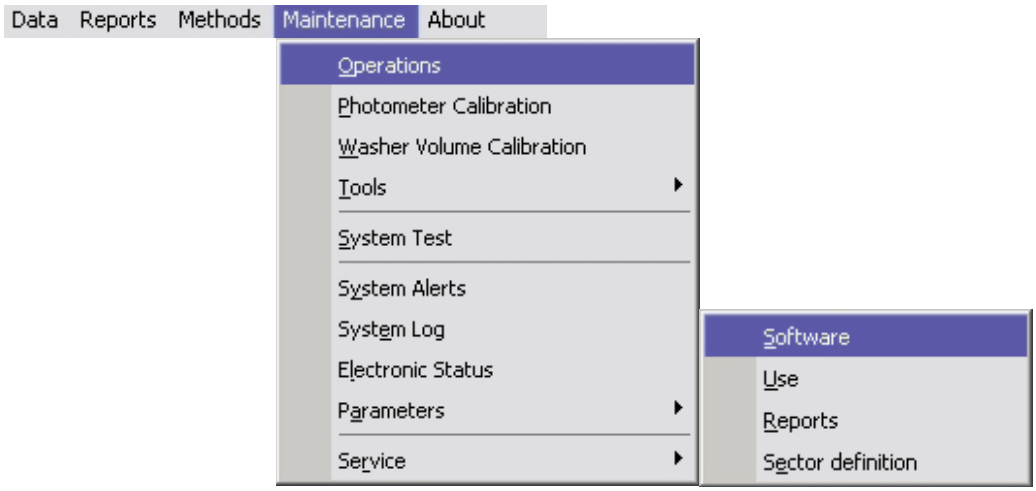
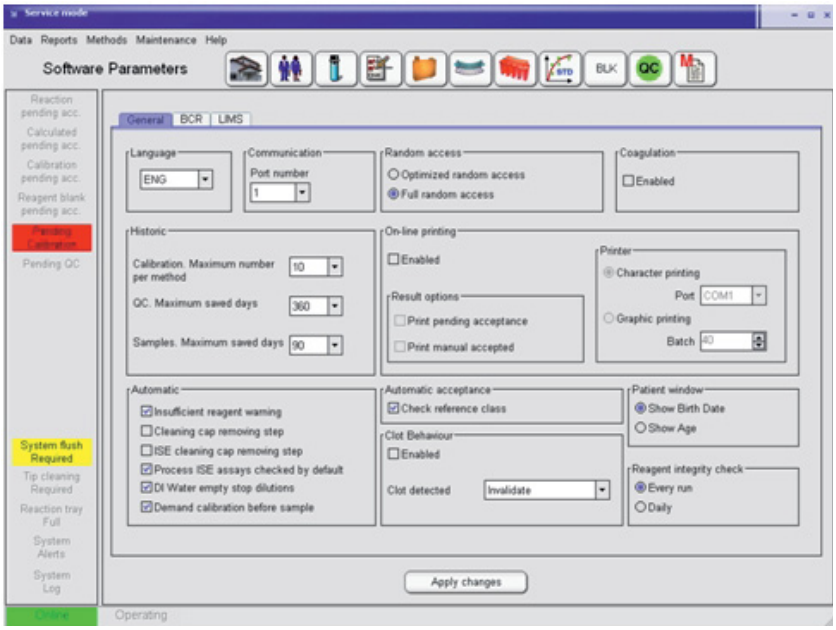


FIGURE 4

General

FIGURE 5



1. Communications. Select serial port according to your computer setting and specification. If setting is wrong, the HumaStar 600 temporarily checks for other port; but if no ports are free, program might not work properly.
2. Language. Select among languages already set in the translator. Changes will come into effect when program is closed and re-opened.
3. Historic. Defines size in days for samples and Controls.
4. Random access.
5. Coagulation. Enables/disables coagulation mode.
6. On-line printing. Enables printing; selector of printout of pending acceptance samples and printout of manually accepted results-
7. Automatic. Selection of active warnings for removing and installation of caps.
8. Automatic acceptance. The automatic acceptance can be conditioned or not by the reference classes values. In other words, it can be programmed that values within the reference class are automatically accepted and the others, not.
9. ISE processing check can be enabled by default with a parameter.
10. The DI empty warning can stop dilutions if checked and issue warning but continue, if not checked.
11. Patient window: selection of display.
    Reagent integrity check: run the reagent integrity check at each start of samples or only once a day.
12. Clot behavior: see section 4.1.1

BCR

13. BCR. Codes can be defined for sectors, samples and reagents. When sectors are provided with bar code identification, it is not necessary to define a number for sector loading.
14. Reagent configuration. Select setting according to your requirements. This selector defines options for Method, bottle type, expiration date format and starting position.
15. Sample configuration. This option enables the use of only a part of code, starting from a given digit and taking a given length. If Id position is not selected, all code digits are read.

LIMS

16. Enabled. Sets communication with host computer.
17. Options. Select parameters according to specifications of your LIMS provider.

3.2.6.2 Use

Use parameters are split in several sections: Cuvette absorbance limits, ISE and definitions of sample vials.

1. Cuvette blanks. Includes upper and lower limits in cuvette testing. Tolerance refers to the allowed absorbance variation after first reading.
2. ISE. User determines if he allows or avoids sample pre-wash. For details, see Section 0
3. Sample vials. Two different sample vials can be defined. This feature is useful to define pediatric vials. Volume calculations require careful section measurement for each defined vial.

3.2.6.3 Reports

This section allows sorting how methods are ordered in report and printout. Keys ***Up*** and ***Down*** allow moving methods to different positions in the final printout.

3.2.6.4 Sector definition

Here user determines if a sector is defined as STAT or not. If so, all samples loaded in the sector will be processed with priority over samples of other sectors. Define a new sector with a number and assign the STAT condition, if required. Be sure that number is not already defined in the column to the right. If so, first delete definition and then re-enter new definition, including STAT condition.

3.2.7 TOOLS

3.2.7.1 Translator

! Always end any modification by pressing the ENTER key.

Translator operates on the language selected in Software parameters.
There are two basic ways of translating: translation control and dictionary. To translate by translation control, place mouse pointer on the screen and phrase whose translation must be modified; press keys ***Shift + Control + C***. The following screen will open:
Left column is the Instrument Internal Language. It is mostly English; second and third column are the present translation, if any. Text may be local or global, that is, can be used only in the selected position or used in different screens. Modification can be local or global. Global modifications affects all entries of the same text. In case of doubt, perform local modifications only.

Modifications take effect only when program is restarted. When a given translation is empty, system will use Internal language, no matter which language is selected.

For translation with Dictionary, select:

Maintenance > Tools > Translator.

When any entry is selected, upper window shows internal text and lower window, the translation, if present.
Sorting can be performed by internal or by translation. There is also a built-in search tool. Entries can be deleted by pressing the corresponding button.

3.2.7.2 Modify reports

Customized report can be modified at will by user in

Maintenance > Tools > Modify Report.

There are four bands that can be added or removed by use of the Add / Remove option. They are: title, header, data and footer.
Title Band includes one option only: title caption. Select in the upper right window the “txtCaption” option and press Edit. The New/ Edit Text screen will show up:

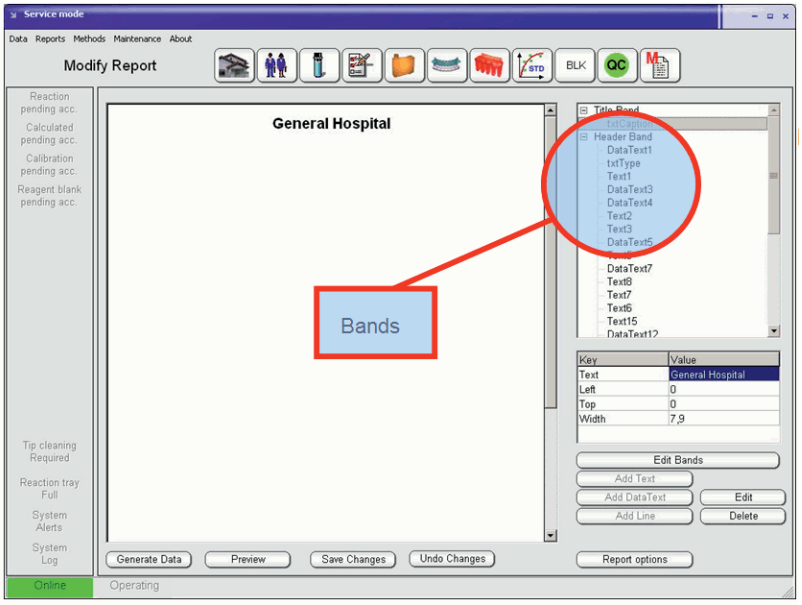


FIGURE 6

Text, position, size, font can be modified in this screen.

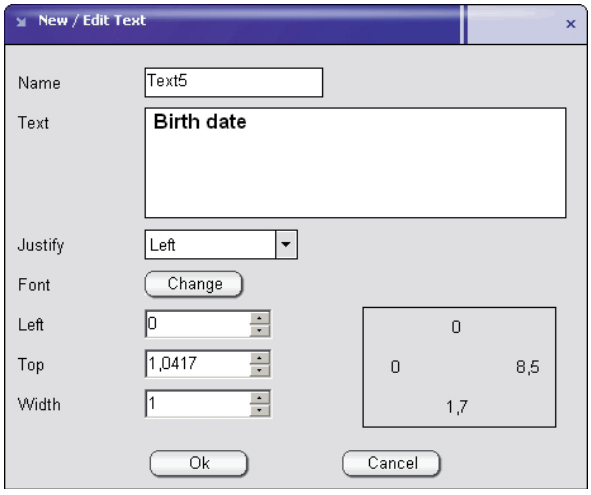


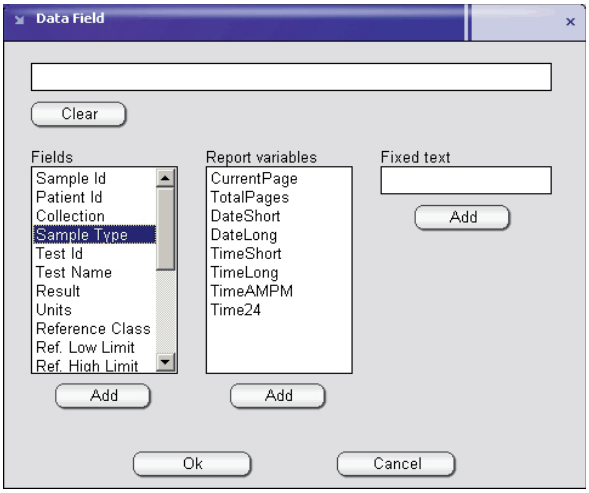
FIGURE 7

Press on the "**+**" symbol in the header band and a complete listing of possible fields will be displayed. There are two types of fields: ***DataText*** are the Results written by instrument once a value is printed. They can be moved, eliminated, changed font, etc. but its text is out of operator's control. There also Report variables that can be added at this time. They include page numbering date and time in different possible formats.

In the New/Edit Data Text, the Change button allows selecting the desired field to be shown. The ***Texts*** are the true headers corresponding to the Data texts and

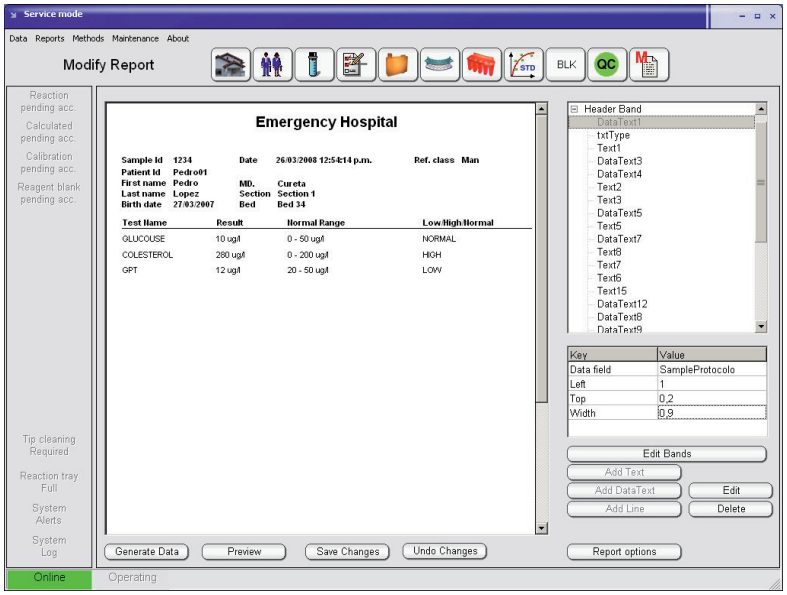
can be fully modified. When the Change button is pressed, the following screen is seen:

FIGURE 8



As an example, the following report format is included in software. User can experiment on adding, removing and modifying printed fields.

FIGURE 9



3.3 Parts of the Instrument

3.3.1 FRONT VIEW

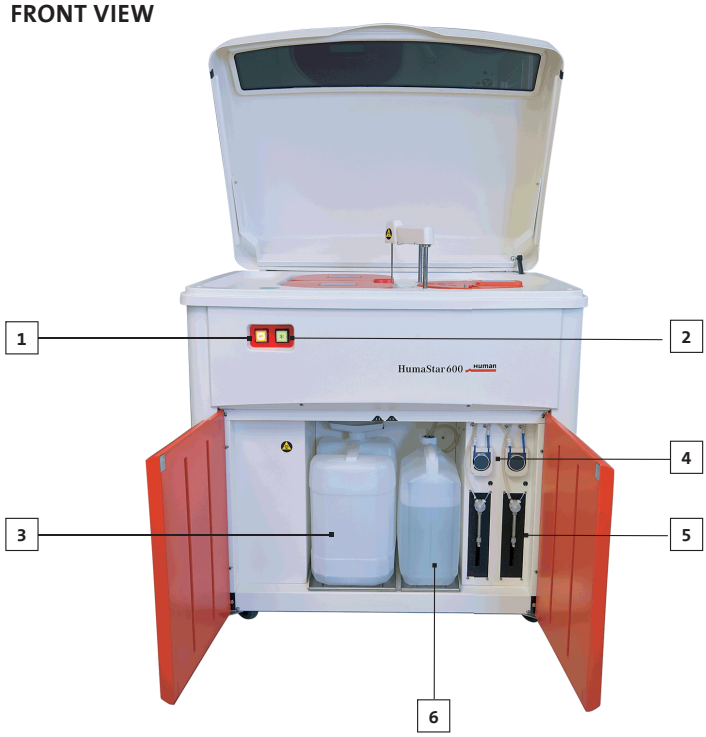


FIGURE 10
Front View

1 On/Off switch
2 Cooling switch
3 Waste tank
4 Washing pumps
5 Front/Back dilutor
6 Wash water

3.3.2 TOP VIEW

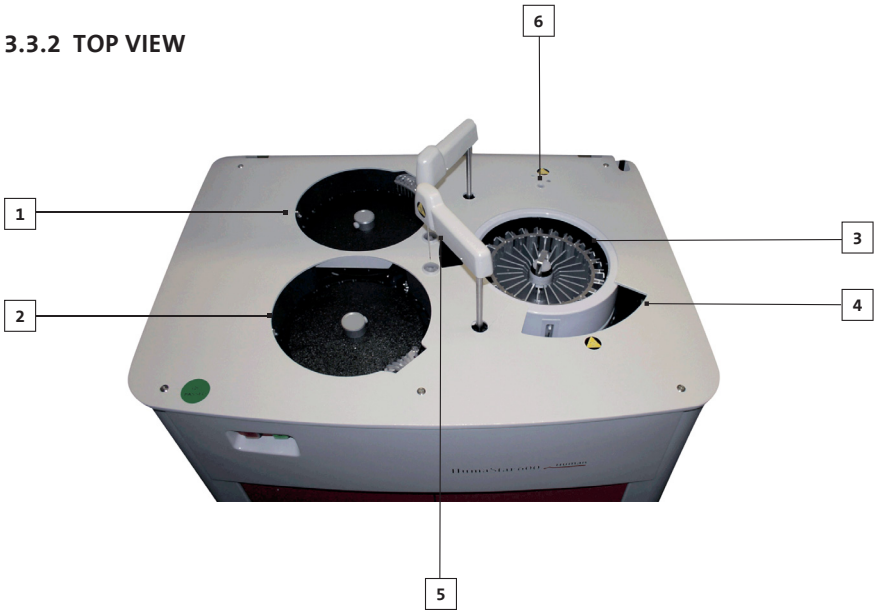
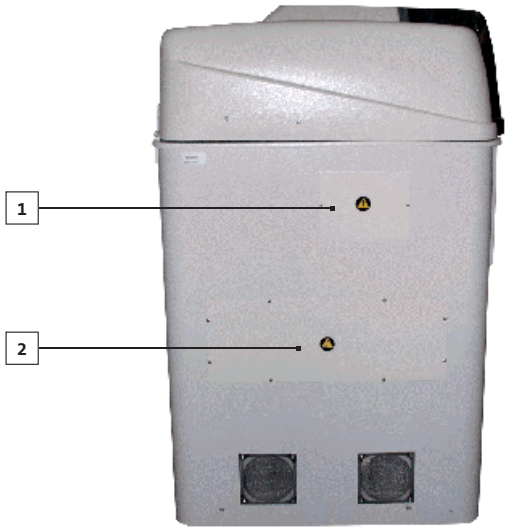


FIGURE 11
Top view

1 Back reaction tray
2 Front reaction tray
3 Reagent tray
4 Sample sectors
5 Front/back pipettors
6 ISE prime reservoir

3.3.3 LEFT SIDE

FIGURE 12



1 Service door for lamp

2 Electronics

3.3.4 SAMPLES AND SAMPLE SECTORS

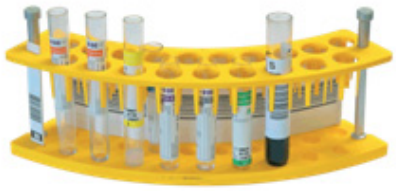
Samples are loaded in a 19 positions sample sector. Continuous p-rocessing is possible by the use of different bar-coded sample sectors, which the user can insert or remove from sample tray during analysis. After loading the sector, samples are immediately identified by direct barcode reading jointly with sample sector type recognition. Five segments can be present simultaneously in the sample tray, while up to 99 external (out of tray) sectors can be handled by the system. STAT samples can be loaded in special high priority sectors to be processed. Standard sector holds 19 bar-coded primary tubes or 19 non bar-coded cups and primary tubes. Special sector for 16 mm external diameter tubes is available upon request.

Sectors can hold:

- micro cup: 0.5 ml
- standard cup: 1.5 ml
- primary tube: 5 ml (13 x 75 mm)
- 7 ml (13 x 100 mm, 13 x 75 mm)
- 10 ml (16 x 100 mm)

FIGURE 13

Standard 19 positions bar-coded sector



3.3.5 REAGENTS

This HumaStar 600 has a cooled reagent tray where 20 ml, 40 ml and 70 ml containers can be placed. The reagent tray includes integrated barcode reader for 24 inner and 24 outer positions. Inner positions can hold two reagents in split containers increasing the total number of onboard reagents to 72 (not available yet). Dilution as well as buffer solutions are also placed in the reagent tray.

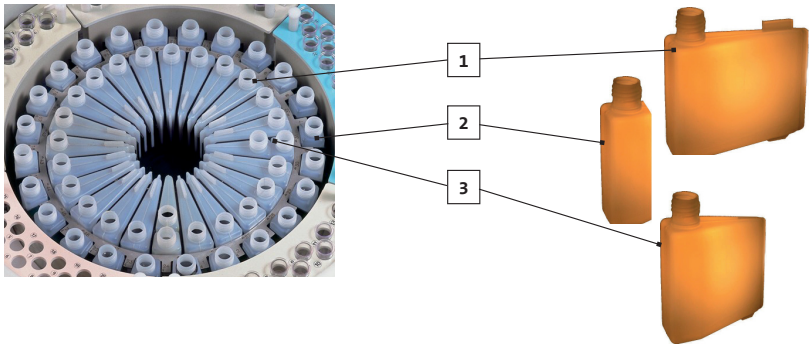


FIGURE 14
Reagent tray and different containers positions

1 **Inner position**
2 **Outer position**
3 **Split Containers (currently not available)**

3.3.6 CUVETTES

Samples and reagents are dispensed into a multiple cuvette strip. Each strip has 5 cuvettes. Reaction trays hold 16 cuvettes strips each, having the system a total of 160 cuvettes.

FIGURE 15
Cuvettes strips

3.4 Software functions overview

The software offers complete functionality to control the instrument and monitor the overall operation which includes: samples and patients management, control reagents, program tests, calibration of methods, perform QC tasks, reactions follow up, statistic on results, among others.

3.4.1 LEVELS OF ACCESS

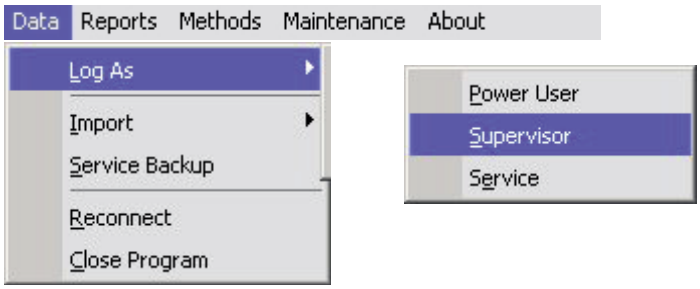
System has different levels of access depending of the type of user:

Operator

- Normal user
- Power user
- Supervisor
- Service

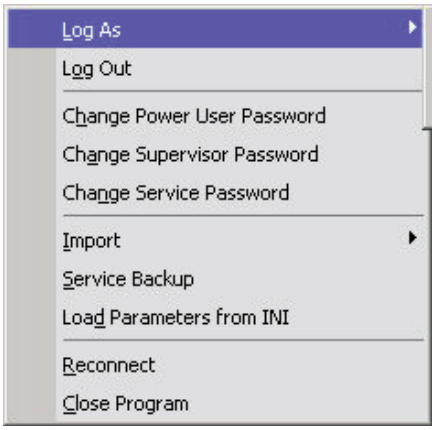
Select in main menu:

FIGURE 16



Select Log as Power User, Supervisor or Service and introduce corresponding Password.

FIGURE 17



Log Out option will return to the operator´s condition. Main menu allows modifying Passwords. Normal User is the default condition. In that case, only operation is possible. Power User can define control sets and calibration sets.

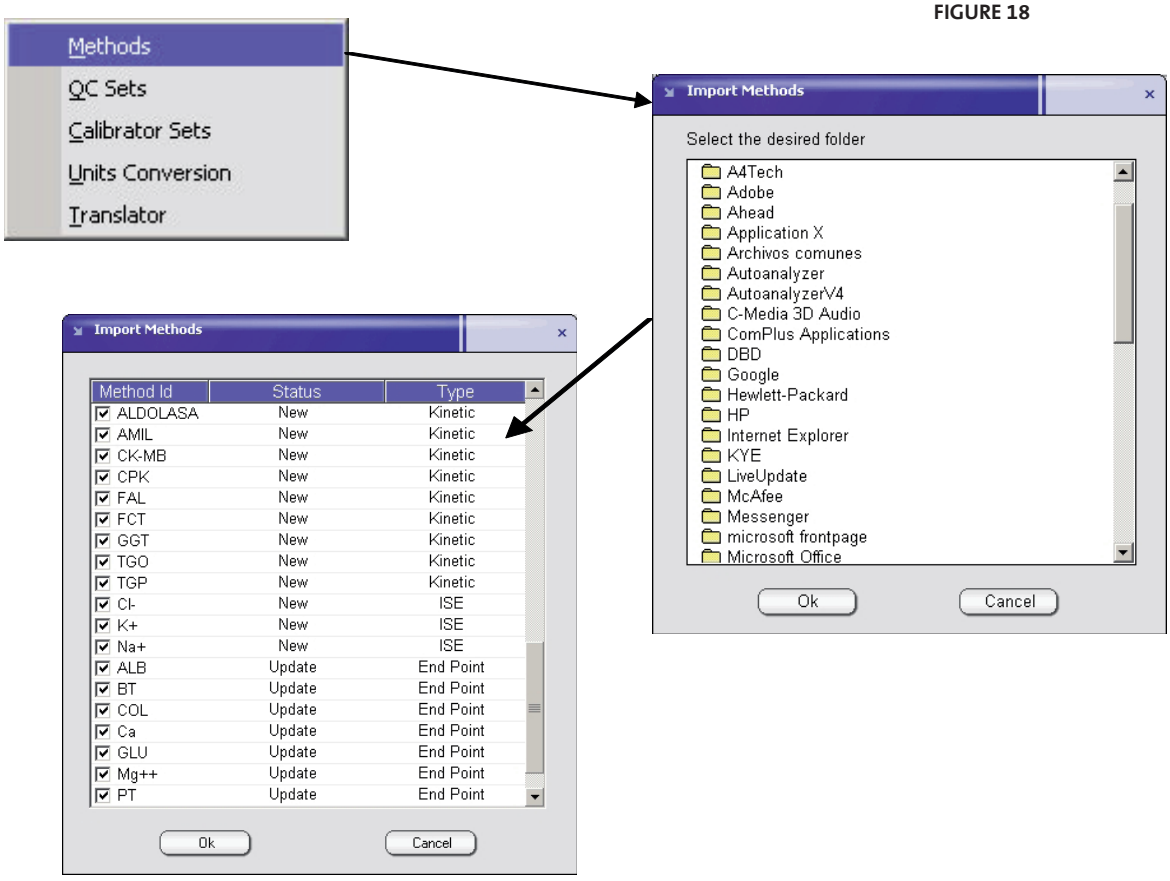
Several actions described in the present manual will be available to Supervisor only. They will be indicated with the symbol:

For actions when use is defined as Service, please refer to the corresponding Manual.

3.4.2 OTHER FUNCTIONS INCLUDED IN DATA MENU

With the ***Import*** function, operator can retrieve several configurations, other than the software database (...\Program Folder\Database). Importable information are, for instance; Methods, QC Sets, Calibrator Sets, Units conversions and Translator information.

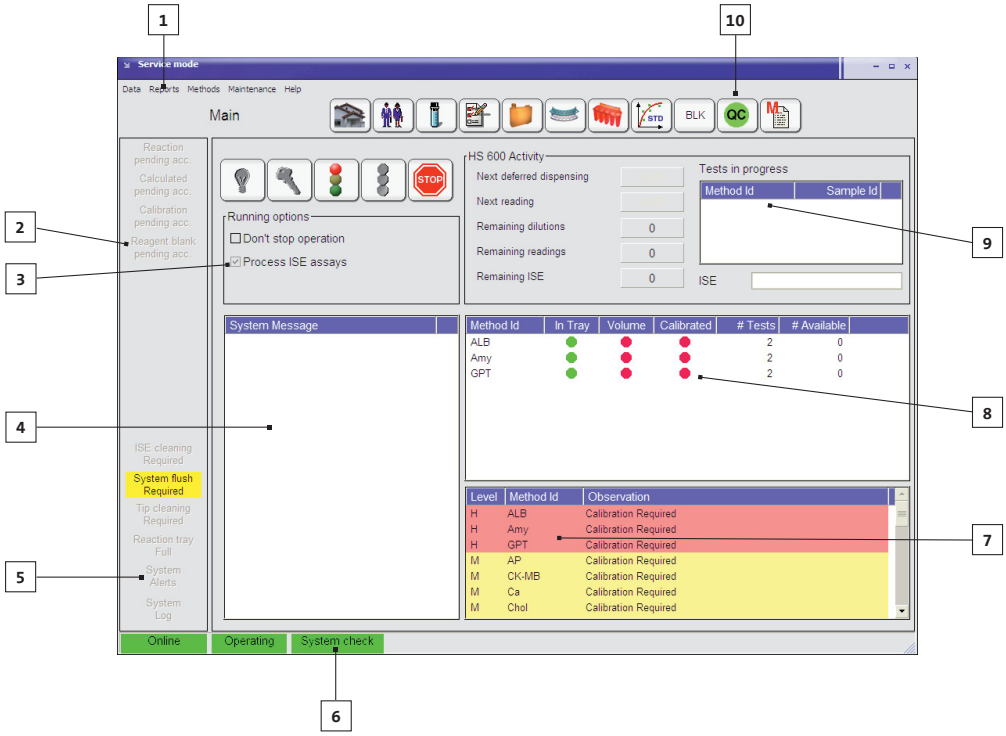
FIGURE 18



The ***Service Backup*** item allows the creation of an instrument image for servicing purposes. The ***Reconnect*** option restarts the instrument hardware operation.

3.4.3 MAIN SCREEN

FIGURE 19
Main Screen



1 **Menu**
2 **Operator requests**
3 **Disable ISE (if available)**
4 **System messages**
5 **System information**
6 **Current activities**
7 **Reagent Information**
8 **Status of selected methods**
9 **Tests in progress**
10 **Quick keys**

Main screen combines the information required for instrument operation, allowing user to check for instrument status and intervention (when required) at a glance. **Quick keys menu** provide direct access to the major program functions.

Main
review the information about current run.

Patients
set demographic data and relevant information.

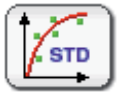
Samples
define and order chemistry, ISE, coagulation and calculated tests.

Tests
review pending reactions and analysis results.

Reagent tray
graphically insert or remove reagents in tray.

Sample tray
load new samples and graphically insert or remove sample sectors in tray.

Reactions
graphically review cuvette usage and change cuvettes.



Calibrations
request or browse pending acceptance, historic and in use calibrations.

Quality Control
request or browse QC and handle statistical functions.

Methods
browse and edit definitions of methods.

Blanks
Definition, review and acceptance of reagent blanks.

Main operation control tool bar gives control over mayor automatic routine operation. Use:

Initialize
to initialize all the instrument units to rest positions.

Start
to begin the routine operation.

Stop
to stop the routine operation.

Suspend and re-start dilutions.
Allows to momentarily stopping dilutions for sample and STAT load.

The Running Options can be selected by operator according requirements which depend on the moment and opportunity.

Non-stop operation: When this option is selected, the automatic cycle does not finish and after sample process instrument is in stand-by condition. This

option is recommended when additional samples for processing are expected soon. When daily work must finish, option must be de-selected.
For daily work end, deselect the option.

Process ISE assays: disable if ISE samples are not expected for the day. This option will not be shown if ISE module is not enabled.

Process Coagulation assays: disable if coagulation samples are not expected for the day.

The bar of requests to operator provide actions requested from instrument to complete some operation such as confirmation of calibrations, confirmation on sample results outside reference class limits, etc. Also, a tip cleaning request is issued if previous cleaning cycle has not been completed.

Messages list registers most relevant notes and warnings the instrument operation can generate such as running out of sample or out of reagent. **Transmission and operating status** displays communication condition between the computer and the instrument (Connecting, Online or Offline and Operating).

Current activity and summary contain relevant information about in progress system operations, phase of operation (Pre-automatic, automatic or post-automatic), next dispensing / reading operation and remaining readings and dispenses.

Test in progress provide the lists of queued test for processing.

Reagent status report shows required reagent volumes to accomplish the processing of the on-tray samples as well as reagent availability. With right click in mouse, options about operations are shown. Information on missing reagents and on missing calibration is also included.

General status bar shows context-sensitive help or information.

Menu bar gives quick and comprehensive access to most program functions

3.4.4 RELEVANT SCREENS

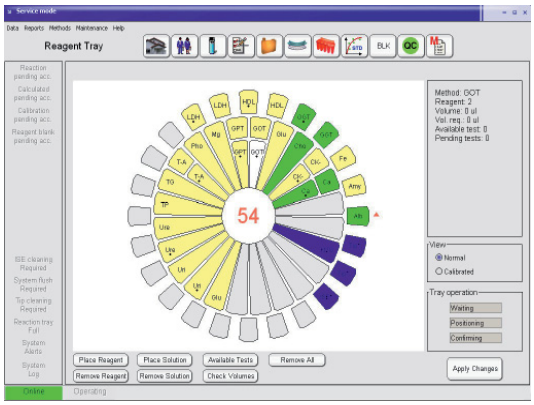


FIGURE 20

From main menu it is possible to access the reagent tray programming to place or remove reagent or solutions.
The second reagent of a given double reagent method will be marked with a dot.
Slide mouse over a reagent on the tray to obtain details on the right panel regarding reagent usage, available volume and pending reactions. Alternative views on reagents and calibration status are available.

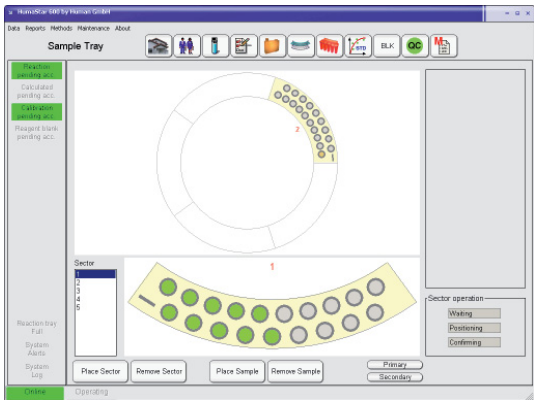


FIGURE 21

Sample tray consists of five sectors of 19 samples each.
User can prepare and load additional sectors while instrument is operating.

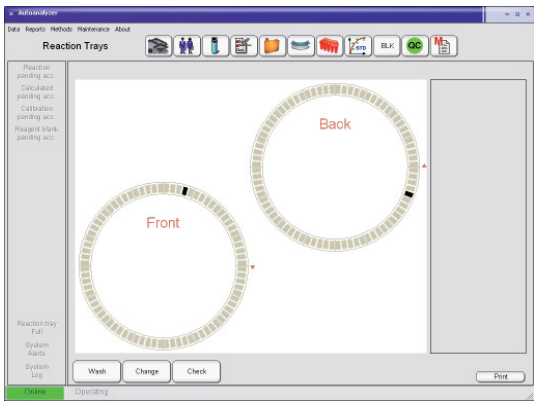
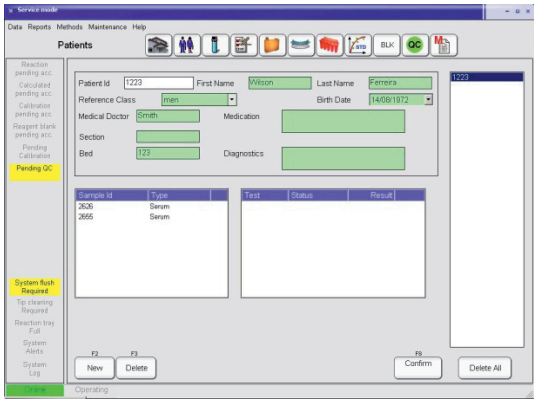


FIGURE 22

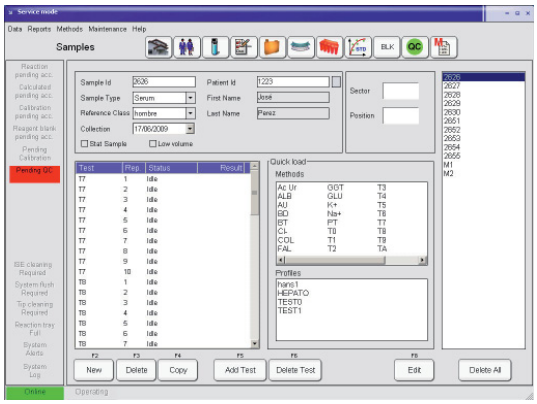
To locate a cuvette corresponding to a certain reaction, click on the reaction tray graph.
Two buttons may be used to force a manual wash of the cuvettes or assert the replacement with new ones.
When this operation is performed motors are disengaged for easier operation and reconnected when done.

FIGURE 23



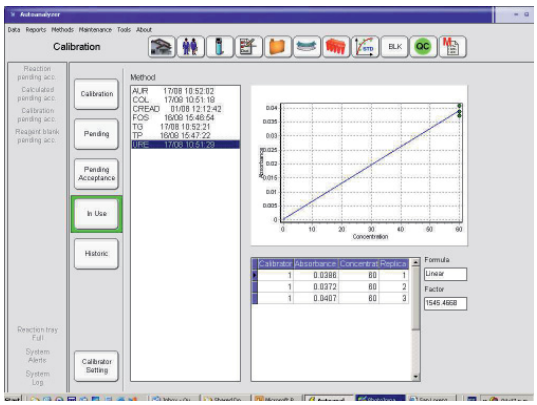
Data such as patient name, sample type, MD, diagnostic can be included.
Also, the assignment of samples to each patient is performed.
For calculated methods, if more than one sample is involved, all must be assigned to the patient.
The patients window can also be accessed directly from samples window.

FIGURE 24

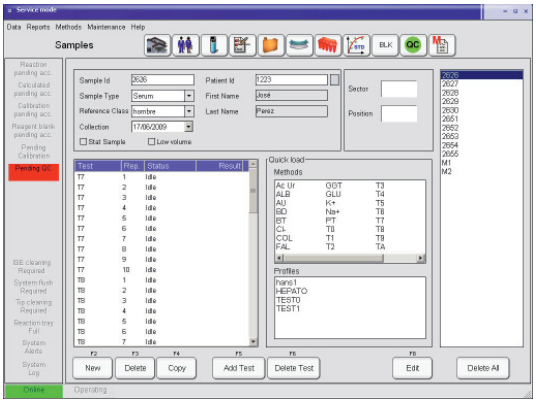


Data from samples are added to this identification screen: Id, type, collection date.
Also, tests and number of replicates are incorporated.
This load can be performed method by method or with the aid quick load and Profile screens.
Patients can be defined with button located to the left of Patient Id.

FIGURE 25



Calibration by a single standard and multipoint methods are carried out by calibration sets.
A calibration set is a group of data defining tests, standard solutions and concentrations, allowing any combination of multi-point and multi-calibrators.
Once defined, user can confirm pending acceptance and browse in use or historic calibrations.



Definition of control sets makes easy check on-board reagent integrity and syst reliability.

Levy-Jennings plot and Westgard m rules are integrated to facilitate analysis.

Twin QC is designed to relate h and low controls and get an accur statistical picture.

Scheduler is designed to program controls pre-set dates.

FIGURE 26

4 GET READY FOR OPERATION

Complete all the steps pointed out in the preceding chapter before continuing.
After verifying correct voltage settings, connect instrument and computer to mains. The suggested startup sequence is:
Turn instrument by pressing the red button on the front (see Figure 10).
Turn printer on.
Turn monitor on.
Turn computer on.
Turn reagent cooling system on by pressing green button lateral on the front panel.
Once operating system is ready, activate the desktop's program icon to open the HumaStar 600 program.
Accept the startup offered by the program, wait until operation finishes and checks there are no visible warning messages on the screen. Otherwise, refer to the troubleshooting chapter in this manual (see chapter 8debajo de).

! Do not change the computer date or time during operation. The current operation will be aborted and all in-progress reactions will be lost.

4.1 Automatic operation

Load of method definitions, samples, analysis, profiles, etc. will be described in detail in the next chapters. Here, the automatic measuring procedure will outlined.
Once samples and reagents are loaded, Main window will show pending analysis, present and required reagents, and any other flagged condition. If one or more samples are not listed, verify that sample sectors are already positioned.

! Pending samples are shown when samples are loaded on tray and tray is already positioned in instrument.

Press the startup (key) button
All system alerts conditions will be tested (wash solution, drain, pump tubing, syringes and blocks cycles). If any debugging condition is set, a warning will be issued at this time.

There are three cycles (shown in the screen):
Pre-automatic
Automatic
Post-automatic
Indication of operation in progress is shown in the screen in green color. Pre-automatic cycle includes initialization, warming up and cuvette testing. System halts if more than 15 cuvettes are dirty in any tray. No new sample entries are allowed in this period. A warning is issued if cooling system is off or defective. No further action is required.

Automatic cycle includes reagent testing, integrity check, dilutions measurements and calculations. Also printouts can be generated in this period.
Post-automatic includes cuvette washing, probe cleaning and conditioning and remaining printout.
If **Non Stop operation** has been selected, instrument remains idle until new samples are introduced or check box deselected.

4.1.1 CLOT DETECTOR

System counts with two clot detectors, one in each probe. They operate based on a differential pressure principle.
Clot detector is installed in
Maintenance > Service > Parameters > Instrumentals > Others
Detectors automatically calibrated when automatic cycle starts. Several working conditions can be adjusted. They are defined in Section 3.4.1:

Maintenance > Parameters > General

and modified with Supervisor privileges.
Systems can be enabled or disabled; if clot is detected, then sample can be repeated or not.
The clot condition will be posted in the details of the sample result.
If sample is discarded, it will continue as in process and a message will be shown in the window of messages in main menu. Clot detector version is posted in the ErrorsLog.txt file.

5 ROUTINE UTILIZATION

5.1 Reagents

5.1.1 REAGENT TRAY

To inspect the on-board reagents press button. The reagents tray window is displayed showing a representation of the actual distribution of reagents in the tray.

! After the placing or removing reagents as described below, user should press *Apply Changes* to start the positioning sequence for reagent placement/removal.

Each bottle shows the first three letters of its method name. When two or more method names start with the same three letters an asterisk (*) is shown for both. One dot under the name indicates second reagent, 2 points a third reagent.

Detailed information of each reagent bottle is displayed in the right panel just pointing with the mouse to the desired position. Each reagent belongs to a certain method. Information includes the owner method name and reagent number, the number of reactions that can be performed with the present volume, and the number of pending reactions for the method. It can be defined more than one vial for each method. If so, when the first defined vial is exhausted the reagent intake will automatically be transferred to the next one.

The colors used for positions allow to easily distinguishing between reagents, diluents, free positions and shorted solutions as follows:

TABLE 3

Green	reagent in position and in use (programmed samples)
Red	reagent not calibrated
Blue	Tip cleaning solutions, diluents and C-Clean
Yellow	Reagent not in use
Light Gray	free position
Dark Gray	reagent not in use or removed

5.1.2 LOADING BAR-CODED REAGENTS

To load bar-coded reagents right click a suitable position and pick ***Change & Bcr check,*** to set the position for a bar-coded reagent position.

Press ***Apply Changes*** to start the positioning sequence for reagent loading into the tray and barcode reading.

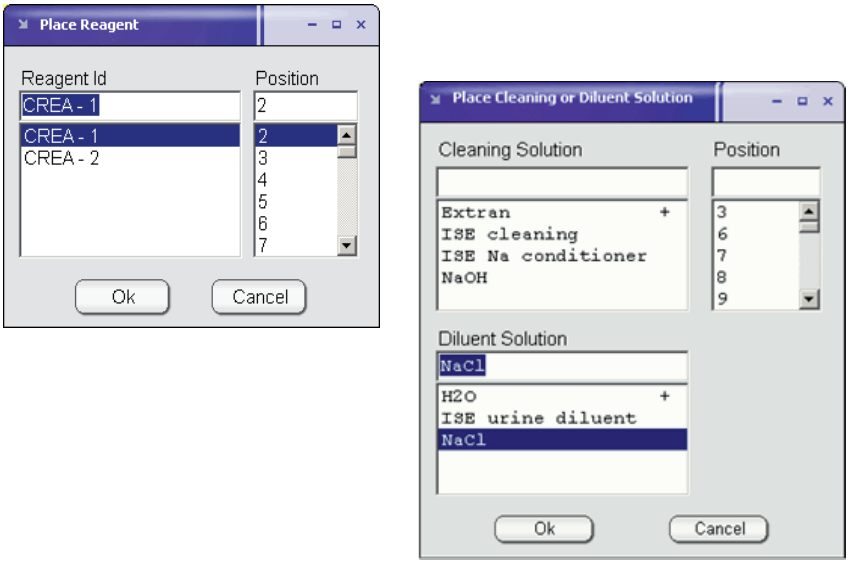
When a reagent is not included in the table of Methods in Use but its code detected as located in the tray, it is automatically included in the methods in use.
When a reagent does not have barcode, in order to speed up the reading procedure, it is advisable to place a Dummy code on it. The Dummy bar codes can be printed by selecting

Reports > Dummy bar code

5.1.3 LOADING NON BAR-CODED REAGENTS AND SOLUTIONS

To define a reagent in to the tray, press ***Place Reagent***, then from the window select or type in the reagent ID field, reagent number and desired position, switching with ***Tab*** key. Press ***Ok*** or ***Enter*** key when done, or press ***Cancel*** or ***Esc*** key to abort. Defined reagent position will exhibit dark gray color.

FIGURE 27



! After the placing or removing reagents as described below, press *Apply Changes* to start the positioning sequence for vial placement/removal.

To define a diluent or cleaning solution in to the tray press ***Place Solution***, select or type in the desired solution and proceed as above.

Alternatively, to define a reagent or solution a particular position in the tray, right click a suitable position and pick ***Place Reagent, Place Diluent Solution, Place Cleaning Solution*** options, select desired reagent or solution. Press ***Ok*** when done or ***Cancel*** to abort.

Even if a reagent is in the tray, a new vial of the same method can be defined. The first loaded will be used first and next, the second one will be checked and used. The "**+**" symbol located in the right side of a reagent means that it is already defined in the tray. There is no limit to the number of vials of the same method in the tray.

Press ***Apply Changes*** and the reagent tray turn the selected position to the bottle insertion area. Message will be: ***Put CREA-1 in position 2***

Open the reagent tray cover, insert the reagent or solution bottle and close the cover.
Then press ***Ok*** when done to confirm the operation.
If more than one reagent is loaded or removed, several messages will be shown in sequence.

! If *Apply Changes* is not pressed, selected positions will remain in dark gray color and cannot be used.

5.1.4 REMOVING REAGENTS AND SOLUTIONS

To remove reagent/s from the tray, press ***Remove Reagent***, select one or more reagent/s or desired positions. Press ***Ok*** when done or ***Cancel*** to abort.

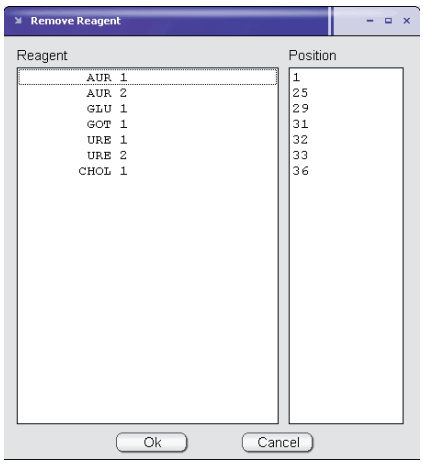


FIGURE 28

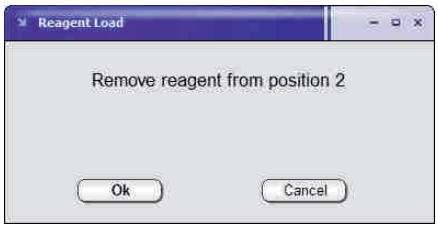
To remove a diluent or cleaning solution from the tray press ***Remove Solution***, select or type in the desired solution and proceed as above.

To select more than one item from the list, press and hold ***Ctrl*** key while selecting the new item. To select a range of items, select the first item, then press and hold ***Shift*** key while selecting the last item. Alternatively for extended selection use the mouse by click and drag.

Alternatively, to remove a reagent or solution from a particular position in the tray, right click the desired position and pick ***Remove*** option.

Press ***Apply Changes*** and the Reagent tray drive the selected position/s to the bottle insertion/removal area. You will read:

FIGURE 29



Open the reagent tray cover, take out the reagent or solution bottles and close the cover.
Next, to confirm the operation press ***Ok*** button when done to confirm the operation.
Same procedure must be followed for removing diluents and solutions.

5.1.5 REFILLING REAGENT BOTTLES (ONLY FOR OPEN CHANNELS)

! Before starting automatic procedure, volumes can be tested. Press *Check Volumes* button for this operation.

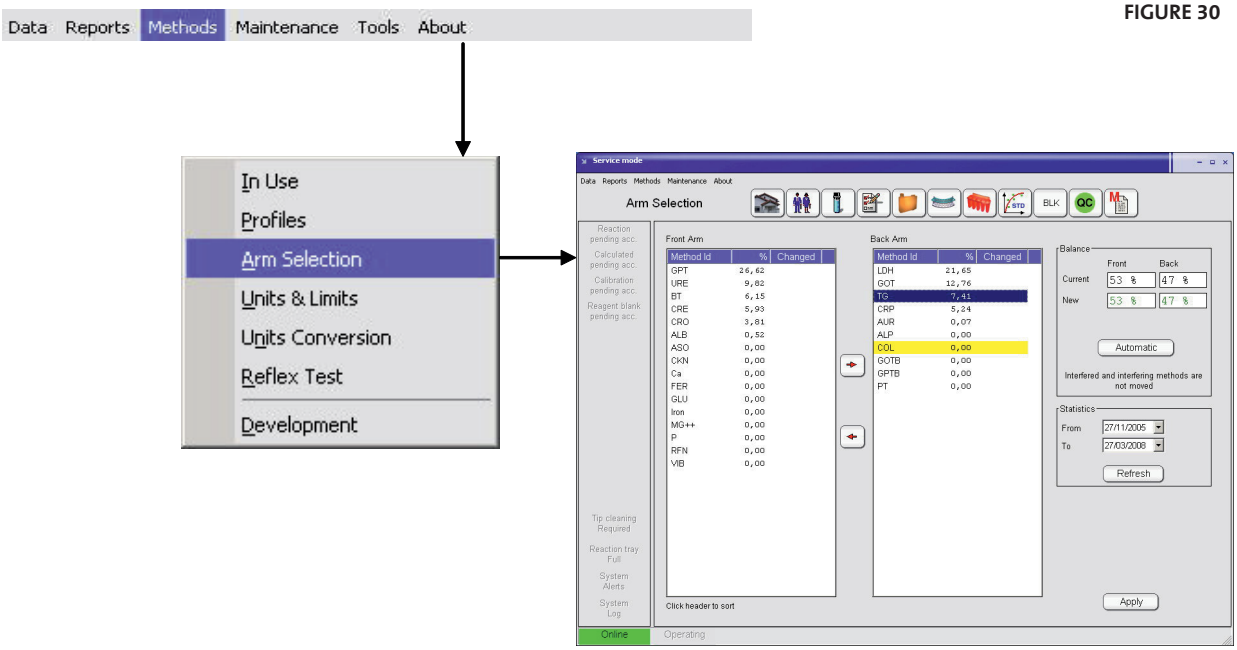
When pressing right button over a given reagent, menu will include a Refill option. Once the ***Apply Changes*** button is pressed, tray will move in the desired reagent position.
Several reagent vials can be refilled with this procedure: when ***Apply Changes*** is pressed tray will sequentially position in all the defined refilling reagents. The dilution restart is automatic.

5.1.6 METHOD ASSIGNMENT TO TRAYS

Methods can be assigned for processing either in the front or back reaction tray. Only those methods defined as Methods in Use can be assigned to a tray. Default assignment is to the front tray.

For tray assignment, follow:

FIGURE 30



There is a unique feature consisting of the possibility of an automatic reassignment of methods to the trays, according historic usage and with the criterion of minimum total analysis time. Automatic reassignment does not include interfering or interfered methods. Interfered methods are posted in red color. To apply it, first ***Refresh*** the desired period for statistical analysis and then press the ***Automatic*** button.
Moved methods will be indicated with an X.

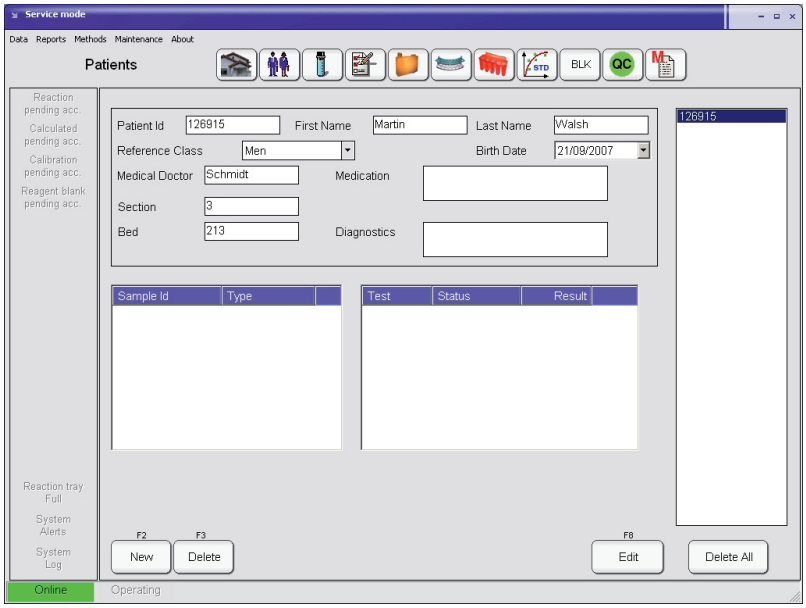
5.2 Samples

Samples can be loaded directly or associated to patients. Chemistry methods are assigned to samples and not directly to patients. External methods are always assigned to patients and calculated methods are assigned to patients and when calculation implies a chemistry measurement, to samples.

5.2.1 WORKING WITH PATIENTS

To create or work with patients press button. The patients' definition

FIGURE 31



Only **Patient Id** is a required field. All others are shown in the patient's report.

Lower left window shows samples assigned to the current patient, the following window (to the right) shows tests exclusively assigned patients (externals or calculated), the rightmost window displays the all defined patients.

Patient ID cannot be modified, unless whole entry is erased. Data are automatically confirmed once written.

Delete All button will remove all samples from the queue.

5.2.2 DEFINING SAMPLE DATA AND TESTS

To define new samples or request tests for a given sample, press the corresponding button. The sample definition window is displayed.

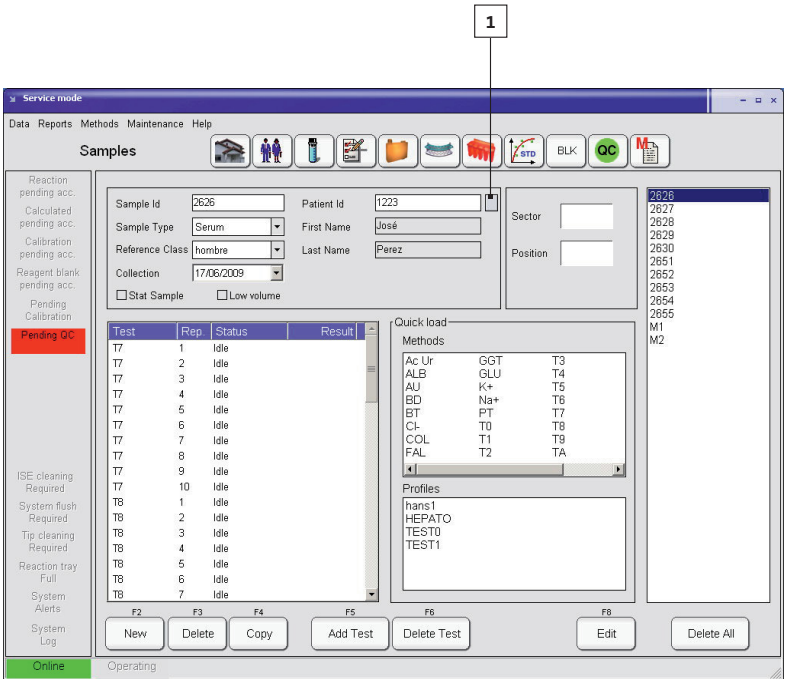


FIGURE 32

1 **Shortcut to patient definition**

To edit information for an already defined sample, first select the sample from the list on the right and then press ***Edit*** button, then press ***Browse*** to switch to navigation mode.

To enter or define a new sample, press ***New*** button. Complete the required information and press ***Ok*** when done or ***Cancel*** to abort.

To request new tests for a sample, first select the sample from the list on the right window and then either:

Press ***Add Test***. Chose from ***Photometric, ISE, External*** or ***Calculated*** type as well as ***profile***, and select or type in the desired method. Press ***Ok*** when done or ***Cancel*** to abort.

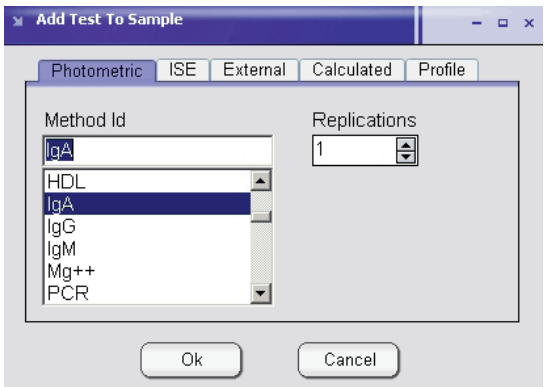


FIGURE 33

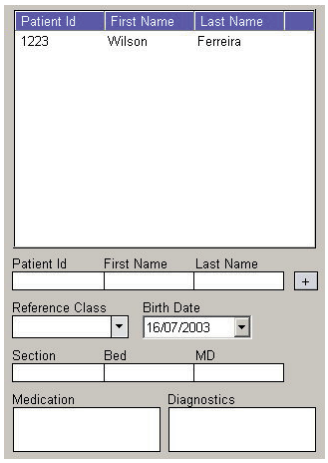
Patient Id, Name and Last Name can be added at this time from a list of already defined patients. When sample is in Edit mode and button located on the right of the Patient Id window pressed, a screen with available Id, Last Names and Names opens and the selection can be made.

Alternatively, double click on the desired methods or profiles, in **Quick load** panel or **Profiles** panel.
When replicates of the same sample are required, use the ***Add Test*** button or press method ID several times in the Quick load window.
Without requiring its introduction in a STAT sector, any sample can be defined as **STAT** at all times by checking ***Stat Sample*** . This will enhance its priority over other samples. For details, see Section 6.2.10.

To define a Test Profile, see section 6.9.

Patients can also be defined directly from the Samples window. By pressing the button located to the right of the Patient Id, the following window opens:

FIGURE 34



If the Patient Id is not generated in this pop-up menu, an automatic patient Id will be created. Its structure will be: **YYMMDD+"."+Sample Id**.
The patient information can be recovered from the historic data when a new patient is created. This is true if the generation is from the patient or the sample window. The software stores one copy of patient information in the historic data. It is understood that a Patient Id defines a physical person.

5.2.3 REMOVING A SAMPLE

To remove a sample from the list press ***Delete Test***:

FIGURE 35

Then press ***Yes*** to confirm or ***No*** to abort.
Delete All button will remove all samples from the queue.

5.2.4 REMOVING TESTS

To remove tests from a sample, first select the sample from the list on the right window and then press ***Delete Test***. Select tests to remove from the list.

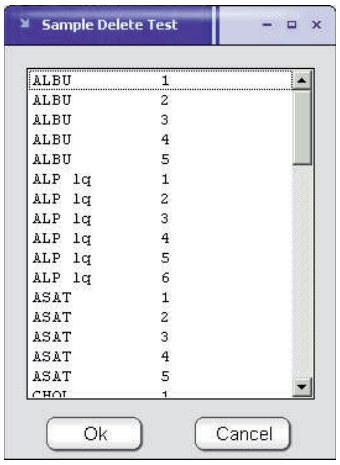


FIGURE 36

Press ***Ok*** when done or ***Cancel*** to abort.

5.2.5 COPY DATA

New samples can be generated by copying data from another sample. Press ***Copy*** button and a window will open for selection of number of replicates. New ID numbers will be correlative to the original one. If alphabetic characters are present in the ID, new digits are added.

5.2.6 LOADING SAMPLES

To manage samples and sample sectors or review the sample tray, press button. The sample tray and sectors definition window is displayed.

To review a sample sector content, just point the mouse over the desired sector on the tray. The complete list of samples will be displayed on the right panel.

To review on-sector sample information, first click on a sector ID from the list of sector or click on an on-tray sector. Then point the mouse over the desired sample position on the actual sector, on the lower panel. The complete list of tests will be displayed on the right panel.
Data are also available for printout in

Reports > Input Tray

Use *Secondary* to set a given sector for use with pediatric or Eppendorf™ vials, press *Primary* to return to primary vial mode or press right mouse button on a given position.

Use *Data > Log as supervisor* and then *Maintenance > Parameters > Use* to set the secondary sample vial section before using this option.

5.2.6.1 Loading bar-coded samples

Be sure that bar code reading is enabled. Access for enabling is in

Maintenance > Parameters > Software (Supervisor only) 

Once a sector is loaded, codes are read for all samples, If samples are not present, reader will reach code located on the rear of sector. Its reading is equivalent to "sample is not present".

When Sample ID is recognized, vial position will match defined sample. If sample ID was not defined in advance, new sample entry is created with recognized ID but user will have to complete data.
If one or more codes are not read by the barcode or are not present, samples still can be measured; a window will open containing the detected non coded samples and operator can accept or reject them.

5.2.6.2 Loading non bar-coded samples, calibrators and controls

To place a sample in a sector, first click in a sector ID from the list of sectors and then press ***Place Sample***. Chose from ***Samples, Calibrators*** or ***Controls*** tab, and select the desired sample and sector position. Press ***Place*** to confirm selection, and then repeat the operation or press ***Exit*** to return. Press ***Place All*** to fill all the free positions in sector with available samples.

To allow samples to be added or removed the sector must be out of the tray. No samples can be added to or removed from an on-tray sector.

5.2.7 REMOVING A SAMPLE

To remove samples from a sector, first click on a sector ID from the list of sectors and then press ***Remove Sample***. Select the sample IDs or sector positions to remove. Press ***Ok*** when done or ***Cancel*** to abort.

To select more than one item from the list, press and hold ***Ctrl*** key while selecting the new item. To select a range of items, select the first item, then press and hold ***Shift*** key while selecting the last item. Alternatively, to extend the selection use the mouse to click and drag.

Before using secondary sample option use ***Data > Log as supervisor*** and then ***Maintenance > Parameters > Use*** to set the secondary sample vial section.

5.2.8 PLACING A SECTOR ON THE TRAY

To place a sector on the tray, first click on a sector ID from the sectors list, then press ***Place Sector***.

The sample tray drives the first available sector position to the sample sector insertion/removal area.

Remove the old sector if any, place the new one.

When done press ***Ok*** button to confirm the operation.

5.2.9 REMOVING A SECTOR

To remove a sector from the tray, first click on the sector ID from the list of sectors or click on an on-tray sector, and then press ***Remove Sector***.

The sample tray drives the selected sector position to the sample sector insertion/removal area.

Remove the sector.

To confirm the operation press ***Ok*** button when done.

! When sectors are coded for BCR reading, it is not necessary to declare the sector number, user will be prompted to put any sector in the first available position. If sector is not coded user must specify any non-used sector position.

5.2.10 LOADING A STAT

All the STAT action is referred to a definition of one or more sectors with that condition. Once defined, the STAT sector has priority over all other sectors.
For sector definition, select

Data > Log as supervisor and then ***Maintenance > Parameters > Sector definition***

Define a new sector with a number and assign the STAT condition. Be sure that number is not already defined in the column to the right. If so, first delete definition and then re-enter new definition, including STAT condition.

5.2.11 REPORTS ON LOAD AND USE

From the menu bar, select ***Reports***. The following menu can be seen:

FIGURE 37

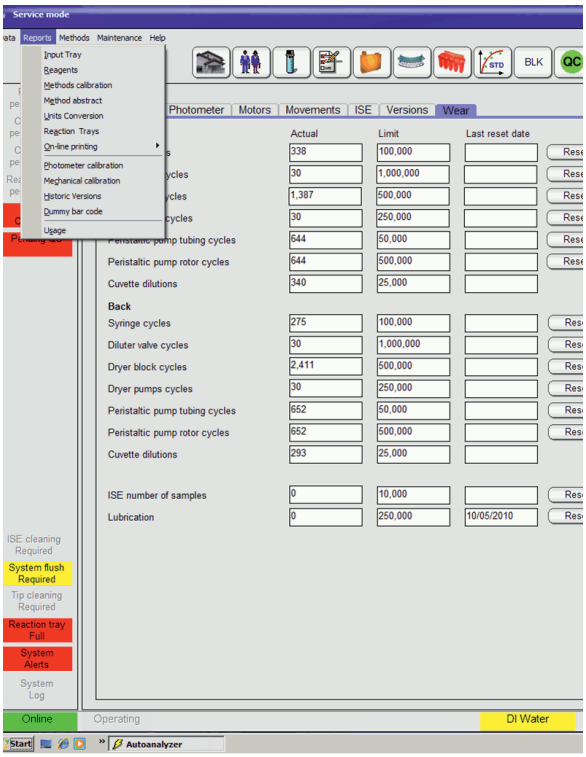


TABLE 4

Input Tray	Data of samples introduced by operator or through LIS.
Reagents	Reagents and solutions already present in tray. Only those used by the programmed samples are shown.
Method abstract	All methods already in memory are listed. Data include ID, name, wavelengths, volumes and times. Methods are classified by type.
Reaction Trays	Cuvette status for all cuvettes in both trays. Data include condition, first empty absorbance measurement and last reading.
On-line printing	When laser or ink-jet printers are used, samples are printed once batch is ready. This option allows printing even if batch is incomplete.
Photometer calibration	Data from the last performed calibration.
Mechanical Calibration	Data on positions measured in steps for trays, arm, washers, etc. Correspond to the last performed calibration.
Historic versions	Correspond to the history of versions for each method, as introduced in their definitions. See section 5.1
Usage	defined for a programmed time interval. Information about ***Run Tests*** and ***Used Reagents*** is available. Option **Used Bottles** is reserved for reagent closed systems.

In all options, the ***Report Preview*** window is open. To print, press the corresponding icon or select ***File > Print***.

5.3 Test results

To inspect sample results press button Window showing results of sample tests classified by categories is displayed.

Press the corresponding button to access the desired category:

Press ***Pending*** tests to review non-processed (idle) or in-progress sample tests.

User must consider that test results may stay idle if the system operation runs out of reagent or sample or the state of reaction is pending blank/pending calibration for a given method.

Press ***Pending Acceptance*** results to confirm or reject processed tests that are waiting for user's approval. During this operation relevant information such as

actual readings, absorbance against the time and blank measurement values will be provided.

Rerun option can be used to retry the reaction.

Test results under this category wait for user confirmation if method's tests are set to manual acceptance (see 5.2.6 for details) and/or the reaction is flagged (see chapter 0 for details).

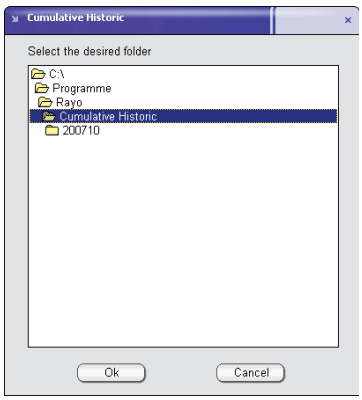
Press ***External*** results to type in values from other sources, usually required by a calculated method.

Press ***Calculated*** to check and confirm calculated method's results.

Press ***Done*** tests to review accepted and rejected results. Results can be filtered with the patient's last name.

Results are also permanently stored. When ***Cumulative Historic*** button is pressed, the following directory will appear:

FIGURE 38



Data are stored in files, each one storing data corresponding to a month and a year. This way results can be reviewed in a very simple manner.

5.3.1 ACCEPTANCE OF RESULTS

To confirm the result for a given test use ***Pending Acceptance***, then select the desired sample test from the list and then press ***Accept***. Press ***Reject*** to reject the test result. To reprocess the reaction just press ***Rerun*** or **Diluted Replicate** if additional dilution could be useful for confirmation of result. A dilution factor can be introduced.

Diluted Rerun
Reject All button will reject all tests pending of acceptance

5.3.2 REFLEX TESTS

Reflex tests are those automatically launched when a given test is out of determined limits. Condition for the reflex test launch can be relative to fixed values or to a reference class.

5.3.3 PRINTOUT OF RESULTS

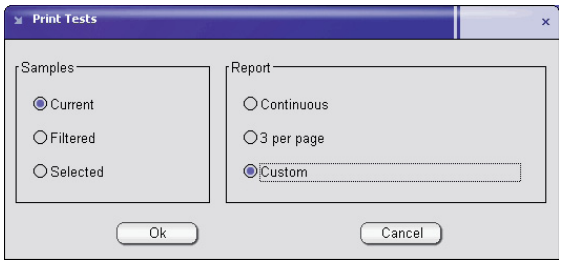


FIGURE 39

Results can be printed out in different ways and operator has full control on the way in which results are shown. This is a Post Run operation and is not related to the On-line printing controlled by Parameter/Software. Button ***Print*** opens the following selector:

Printing can be performed on all samples, some filtered or selected. Selection can be made by pressing Control Key while pointer is pressed on selected samples. A range is selected by pressing mouse on the first and then pressing Shift key and pointing to the last one of the desired ranges.

There are three types of reports: Continuous: samples are printed out one after the other; 3 per page according a fixed report format; Custom, according report made by use of the Report Format Generator, as explained in ***Tools > Modify Report.***

5.3.4 CUVETTE

Report for use for service engineers only.

5.4 Calibration

To enter a new calibration or define a calibrator set, press button.
The calibration definition window is displayed showing different items as follows.
Press ***Calibration*** to order a new calibration over one or more methods.

Press ***Pending*** tests to review non-processed (idle) or in-progress calibration tests.
User should consider that test results may stay idle if the system operation runs out of reagent or calibrator.

Press ***Pending Acceptance*** to confirm or reject processed calibration tests that are waiting for user's approval. Rerun option can be used to retry the reaction.
Accept and ***Reject*** can only be activated by the Supervisor after log-in.

Test results under this category wait for user confirmation if method's calibration tests are set for manual acceptance (see 6.4.4. for details) and/or the reaction is flagged. Press ***In Use*** calibrations to review the actual method's calibration details.

Press ***Historic*** calibrations to review and use former method's calibration details. Historic calibrations can be used again. To do that, select the desired calibration and press the ***Reuse*** button. The selected calibration will be shown in the screen of calibrations ***In Use***. This resource must be cautiously used and prevent errors of calibrating with reagents of different lots. Also, it should not be misused or mixed with other active calibrations.
Automatic method calibration configuration

Press ***Done*** calibrations to access ion selective module calibrations.
Press ***Calibrator Sets*** to define the profile of a commercial standard.

5.4.1 CALIBRATOR SETS

Calibrations are structured by means of calibrator sets. A calibration set represents the cluster of methods a commercial calibrator can be used for. Once the customer defines a few calibration sets, it's easy to order calibrations based on any of them.

To access to calibrator setting button, enter to ***Data > Standards*** and then press ***Calibrator Set***.

5.4.1.1 Defining a calibrator set

To edit the definition of an already defined calibrator set, first select the calibrator set from the list on the right and then press ***Edit***.

To enter or define a new calibrator set, press ***New***.

To add a new method to the calibrator set press ***Add Test*** and select or type in the method ID. Then type in the calibrator number and concentration, and press ***Add***. Define the number of default **Replicas** for each method.

Repeat this operation for each standard on the set. Press ***Ok*** when done or ***Cancel*** to abort.

To remove a method from the calibrator set, press ***Delete Test***.
Once no further modifications are required for the calibrator set, press ***Ok*** to finish or ***Cancel*** to abort.
Once tests are loaded in the grid, concentration values can be edited at all times.

5.4.1.2 Removing a calibrator set

To remove a calibrator set from the list, select the calibrator set from the list on the right and press ***Delete***. Press Yes to confirm or No to abort.

5.4.1.3 Automatic Dilutions

It is possible to build up a full set of calibrators as dilution from a high concentration calibrator. When ***Add Test*** is pressed, the following screen will show up:

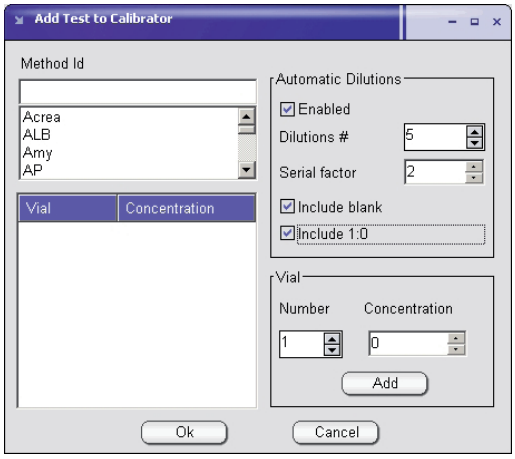


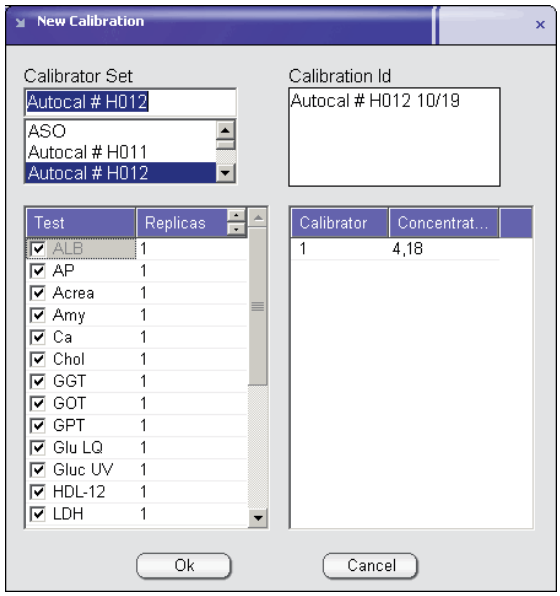
FIGURE 40

The window for automatic **Dilutions** will show the number of dilutions that integrate the curve. The **Serial factor** indicates the dilution factor: a factor of 2 will define the concentration as 1/2, 1/4, 1/8, etc.; a factor of 3 will define concentrations as 1/3; 1/9; 1/27; etc. The set optionally can include or not the mother solution and the blank. If included, they are within the defined number. The concentration of mother solution is defined in the **Vial** sector. A minimum of 2 standards and a maximum of 10 standards are accepted.

5.4.2 REQUESTING A CALIBRATION

To request a new calibration based on a calibrator set, press ***New*** and select or type in the desired calibrator set. Edit the calibration ID if necessary and check at least one test you want the calibration to take into account.

FIGURE 41



! The instrument will automatically adjust the number of times this procedure is repeated for completing all requested standards and replicates.

Press ***Ok*** when done or ***Cancel*** to abort.

To request at a later time another method from the calibrator set, select the calibration from the list on the right and press ***Add Test***. Check one or more tests you want to add. Define the number of replicates. They can be equal or different for different tests. Press ***Ok*** when done or ***Cancel*** to abort.

From the historic calibration window, the operator can reuse an old calibration

5.4.3 ORDERING A CALIBRATION

To load the calibrator's cups on the instrument sample tray refer to section 0.

5.4.4 CALIBRATION ACCEPTANCE

To confirm a calibration test result, press ***Pending Acceptance*** and choose the desired method.
It is possible to disable individual replicates by de-selecting from the calibrator column.
Column to the right of each function will show the least squares adjusting value. Select function with minimum value unless some special feature is required.
Experiment de-selecting one or more standards and observe recalculated values.
Press ***Accept*** once the calibration curve and values are as desired. In this case, at least one value for each vial must be selected.
Press ***Reject*** to mark the calibration as unusable.
Accept and ***Reject*** can only be activated by the Supervisor after log-in.

5.4.4.1 Flagged results

Press ***Show details*** to expand the detailed area for the selected reaction. This panel points out active flags. Results may be flagged if validity limits, duplication limits or reference class limits are exceeded. Both low and high limits can be set independently (see chapter 6.2.4 for details).

5.4.4.2 Calculations

There are several built-in adjusting formulas in the system.
They can be all shown if available. They are:

Linear

TABLE 5

Multilinear	linear interpolation between consecutive standards.
Spline	consecutive 3d degree polynomials joining consecutive data.
Sigmoid	Abs = L + ((H – L)/(1 + exp(-(Conc – a)/b))) where H, L , a and b are automatic adjusting parameters.
Logit5	Abs = R + (K/(1 + exp(-(a+b*ln(Conc) + c* Conc)))) where K, a,b,c are automatic adjusting parameters.
Logit4	Abs = R + (K/(1 + exp(-(a+b*ln(Conc))))) where K, a,b are automatic adjusting parameters.

Calibration fit parameter is shown in all cases.
If curve is forced to pass through zero, functions logit 4 and logit 5 will diverge because of the logarithm function and will not be shown.
Logit5 requires a minimum of 5 standards; logit4 requires a minimum of 4 standards; sigmoid and multi linear functions require a minimum of 3 standards.

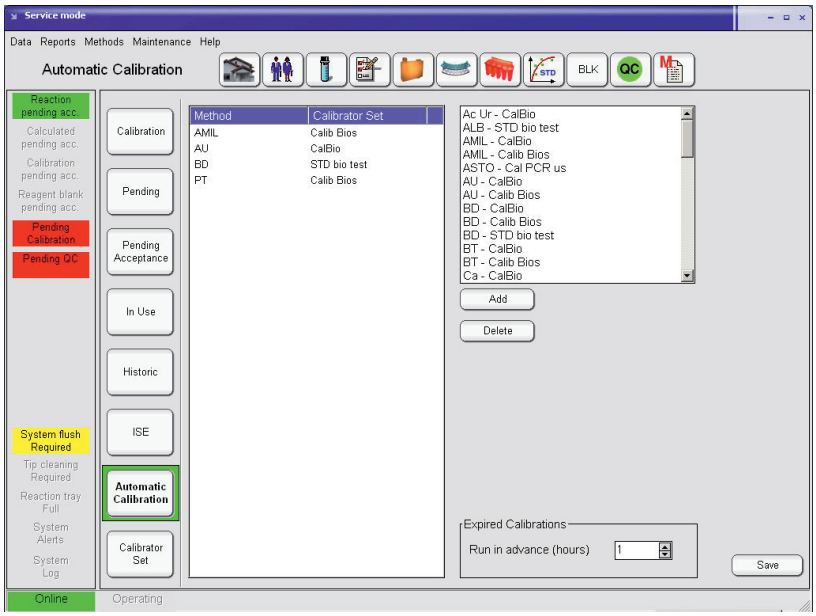
5.4.5 AUTOMATIC CALIBRATION

It is possible to define for each method, which Calibrator Set will be used in the next calibration, once the present one is expired, deleted or changed the lot number. This set can also be “Run in advance” and be ready several hours before the present calibration expires. By selecting

Standards > Automatic Calibration

the operator can select from the right window the desired Method/Calibration Set combination. With the corresponding button the Run in advance interval is also fixed. This interval is checked every 15 minutes when not in automatic mode and when software or automatic start.

FIGURE 42



5.5 Blanks

Blanks can be measured in the automatic procedure or directly from the BLANK menu.

When the automatic starts, blanks are requested for the following reasons:

1. It was not measured before
2. It expired
3. Reagent was removed, refilled or changed.

In that case, a window opens with the list of required blanks. User can include the number of required replicates.
When button is pressed, there is access to the blank options.
When ***New*** is pressed, the following screen opens:

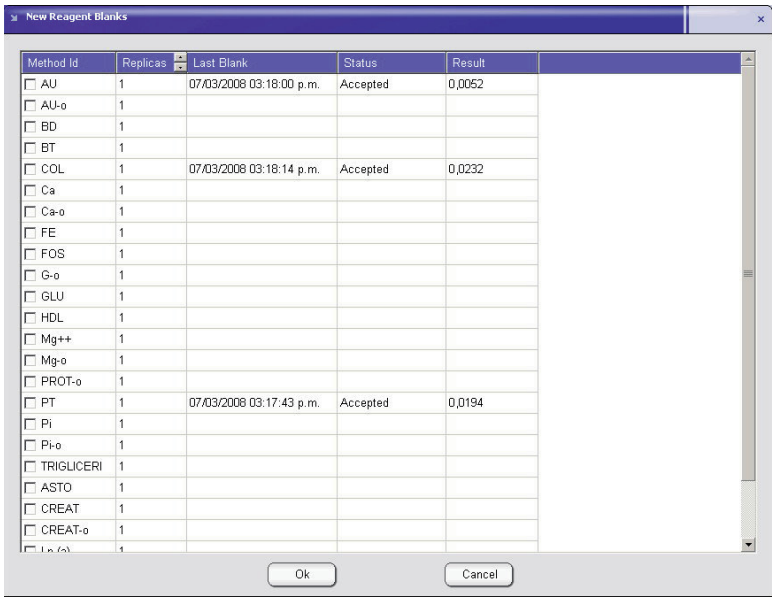


FIGURE 43

Table shows last measured absorbance and its date. By checking and adding the number of replicates, blanks can be measured.
The menu of blanks also shows the blanks ***Pending Acceptance***. Pending of Acceptance. When replicates are taken, operator can accept or reject them individually. Final result is the average of all accepted values.
Accept and ***Reject*** can only be activated by the Supervisor after log-in.

Blanks ***In Use*** can be observed and ***Historic*** results also analyzed.

5.6 Quality control

Quality control system is based on the use of ***Control Sets***. A control set is a vial of a given brand and lot containing all the desired analytes with their respective admissible ranges. Control sets from different brands and levels can be defined. Once the ***Control Set*** is defined, it is daily used by defining a ***Control*** and selecting from the set the desired analytes and number of replicates. New Control Sets must be defined when a new lot is available and new admissible ranges are defined.

To request a new control or define a control set, press the button. The quality control definition window is displayed showing different items as follows.

5.6.1 CREATING A CONTROL SET

Press the ***Control Set*** button.

To define a new control set, press ***New*** . Define control set id, introduce lot number and expiration date for traceability purposes and filtering options.

To edit the definition of a already defined control set press Control set and select the control set from the list on the right and then press ***Edit*** .

To add a new test to the control set press ***Add Test*** and select or type in the method ID. Then type in the concentration range for that method and press ***Ok*** to add the test or ***Cancel*** to abort. To remove a method from the control set, press ***Delete Test*** .

Define the number of default ***Replicas*** for each test within each control set. This number will be used every time the control set is used or scheduled.

Repeat this operation for each required test on the profile. Then press ***Ok*** to finish or ***Cancel*** to abort.

Alternatively, double click on the Quick load list and replace zeros with the low and high limit values.

Once tests are loaded in the grid, concentration limits can be edited at all times.

To remove a control set from the list, first select the control profile from the list on the right and then press ***Delete*** . Press ***Yes*** to confirm or ***No*** to abort. ***Delete All*** button will remove all control sets

5.6.2 REQUESTING A CONTROL

To request a control based on a control set, press ***Controls*** button and then ***New*** and select the desired control set. Select at least one test to be performed and the number of replicates. When double click is acted on the Test title band, all tests can be selected or deselected together. Replicates can be set individually or the whole set by performing the selection on the title bar. Press ***Ok*** when done or ***Cancel*** to abort.

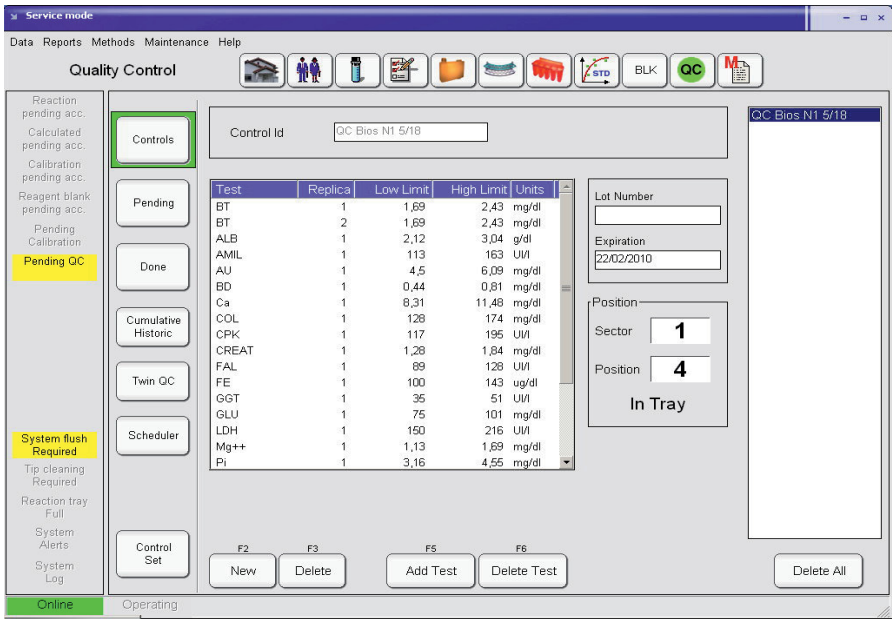


FIGURE 44

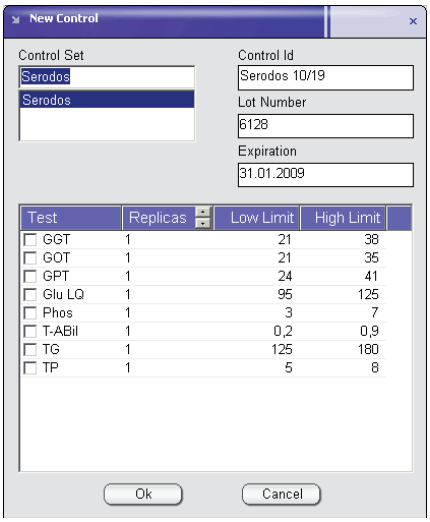


FIGURE 45

Control Id is automatically generated by adding the date (day and month) to the Control Set Id. This Id can be modified at the moment of generation but not at a later time.

New tests included in the Control Set can be added later: select the control from the list on the right and press ***Add Test*** . Check one or more tests that you want to add. Press ***Ok*** when done or ***Cancel*** to abort.

To remove a test from the control press ***Delete Test***. Select one or more tests from the list. Press ***Ok*** to confirm or ***Cancel*** to abort.

5.6.3 PROCESSING A CONTROL

Once the control has been requested, load it in a vial and place in the instrument as indicated in 0.

If the barcode reading procedure is performed and a control set is recognized, it will be associated with any pending action already defined in the scheduler. If not programmed in scheduler, no action will be taken on the control.

Press ***Pending*** tests to review non-processed (idle) or in-progress control tests.

User must consider that test results may stay idle if the system operation runs out of reagent or control sample.

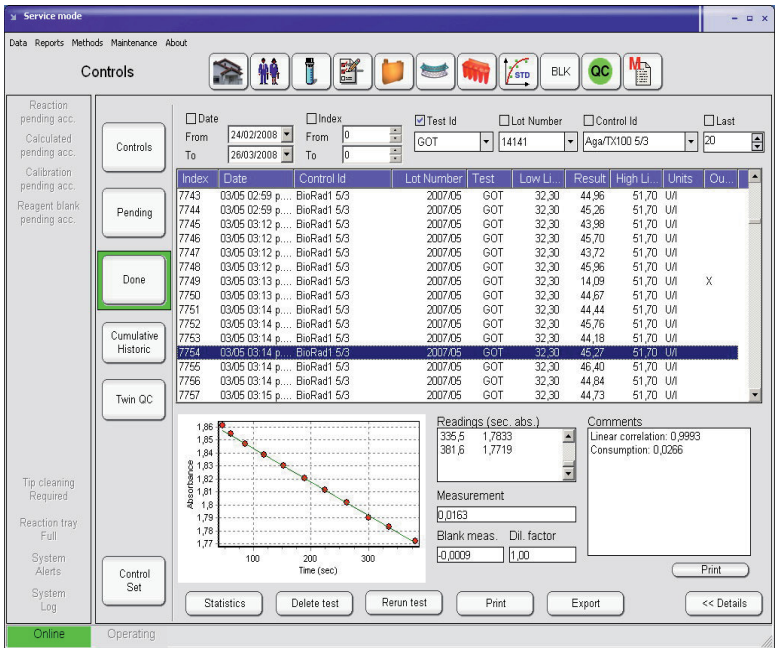
Press ***Done*** control tests to review former method's controls details.

Press ***Cumulative Historic*** to review data already stored in previous runs. They will be organized in directories, where results of each month are automatically stored.

5.6.4 PROCESSED CONTROLS. STATISTICS

Controls already processed are shown when pressing ***Done*** as shown below:

Use upper selector to set the filter properties with one or more of the following items:



Date selectors show calendar for simple selection. All results are indexed and index is shown at the beginning of each column. Selectors can be used separately or together. Selectors act as logical and allows refining the selection.

When ***<<Details*** button is pressed, screen shows information about time evolution, interval correlation, etc.
Statistics can be applied to filtered data:

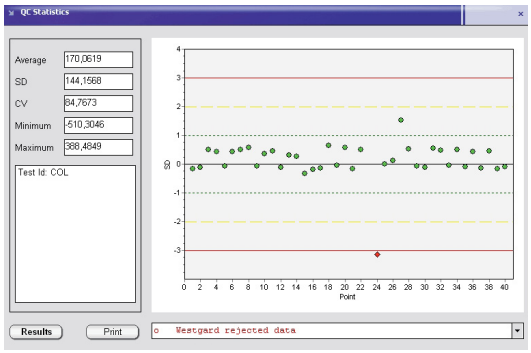


FIGURE 46

Graphics shows relevant statistical data, Levy-Jennings diagram and Westgard rules violations. Data can also be printed out. When Results button is pressed, the complete list of results is shown. Individual data can be temporarily disabled for studies of effects of different data on the statistics.

5.7 Twin QC

Twin QC operates on quality controls already performed and its purpose is relating high and low controls and getting Youden plots and correlated Levy-Jennings plots.
Youden Plot is a bi-dimensional plot where correlated data for two-level systems or normal/abnormal data, taken in the same run are represented.

For operation, proceed as follows:

1. Define a Twin set. Print the Twin definition button
- Define a name which defines a given set of controls.
- Select the prefix for the high and low (or normal/abnormal) levels. It is important that they must coincide with the selections included in the Control Id column of **Done** controls. In the example shown here: QB BIOS N1 and QB BIOS N2. The identification after N1 and N2 is irrelevant.
2. Link the samples. Press Link Samples button. Window will show all controls which correspond to high level in the second window and to low level in the third window. Click the mouse on a high level item and next to the correlated

! Coupled quality control is a useful tool if both controls of each pair are taken in similar conditions. Observe index number, date, time and lot number and verify that data were taken in close conditions.

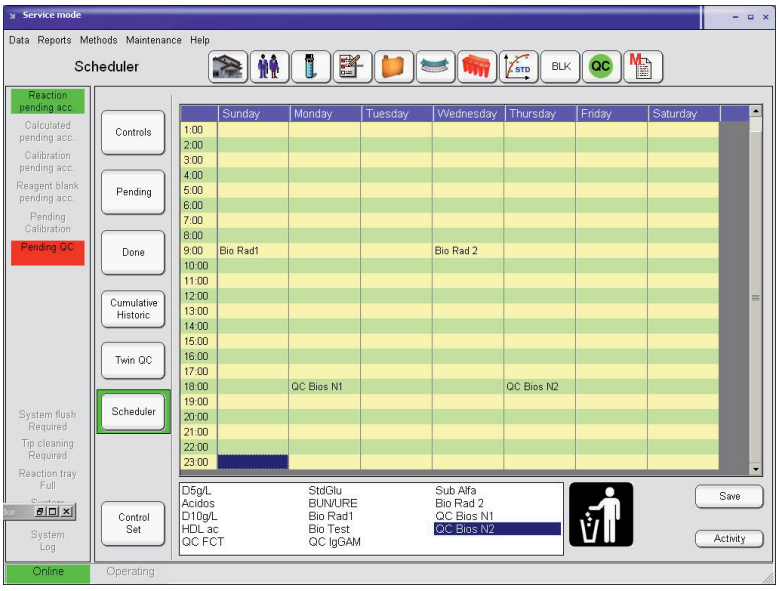
low level item. Once they are selected press the Link button. Press Statistics. Linked entries will appear in the upper (Linked) window. For identification purposes entries will be shown in alternate colors yellow and white. Every entry can be unlinked by selecting one of both components and pressing the ***Unlink*** button.

3. Select the desired method, and the initial and final date for the study.
4. Youden Plot. This statistical technique involves both normal and abnormal controls and graphically helps to differentiate between systematic and random errors. The square represents +/- 3 standard deviations for both controls. Red circle represents SQR($SD1^2$ + $SD2^2$) = 2. The two median lines (vertical and horizontal axis) represent zero error normal and abnormal controls, respectively. The intersection of both median lines is called the Manhattan Median. The diagonal through the Manhattan Medial is the ideal location, high correlation position for the pairs. Points near the line but outside the 2SD circle indicate a systematic error. Points that lie far from the 45-degree reference line indicate a random error.
5. Levy-Jennings plot. This plot represents standard deviation data for both controls. Also, several Westgard rules can be applied to both sets.

5.7.1 QC SCHEDULER

QC scheduler allows programming in advance all the QC actions on a weekly basis.

FIGURE 47



The defined controls are shown in the lower part of the screen. They must be dragged and dropped in the desired hour and day and then saved by pressing the corresponding button. They are immediately in the Pending QC status shown in red in the left side of the screen. They can be removed by dragging and dropping on the trash symbol.
They remain as pending until they are in the list of programmed samples and all the included reactions are processed. The Activity shows the next programmed action on each control, but they are due immediately after programming. If only some test are pending, warning flag will be in yellow color.

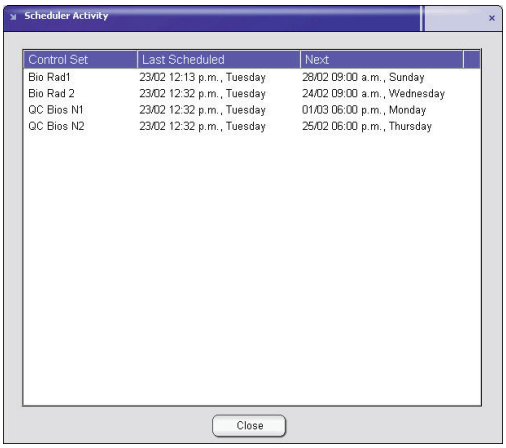


FIGURE 48

5.8 Working with LIS

The use of information management systems is widespread in hospitals and health centres where data must be collected from different kinds of instruments. The LIS (or LIMS) capability provides a reliable way for information interchange through ASTM E1381 and E1394 standards.
Results from accepted tests may be transmitted automatically to the host computer by the Autoanalyzer software, upon request from the host computer or manually at any time upon user demand.
Possible settings in the LIS page (-> Maintenance -> Parameters -> LIMS – Options) see below.

Auto send results. The results are send to the LIS when a test is manually or automatically accepted.

Only order by LIS. Only send results from tests required by the LIS system. Manually programmed tests are not send.

Auto request tests. When a new sample is created a query to the LIS system is generated in order to obtain the test for that specific sample. A sample can be created manually from the sample window or by the barcode reader. If the BCR read a sample that already exist the query is not generated because is supposed to be generated at creation time. This same query will be send to the LIS if you push „LIS req." button in the sample window.

Send QC results. If the software should send QC results to the LIS system.

Send calibrator results. If the software should send calibrator results to the LIS system.
Also the software allows to answer querys from the LIS system in order to obtain results.

How query mode works and what to do in order to work with it
I should first try to establish communication with the LIS system. Uncheck „Auto request test" option and apply changes. Go to Data->LIS->Communication and erase any previous log. Then, from the sample window, create a new sample and push „LIS req." button. Go back to the LIS communication window and you will see the {ENQ}. The same way the software works when the „Auto request test" option is selected, except that there is no need to push the button. You can now check this option, create a new sample and you will observe the same behaviour.

5.8.1 ASTM STRUCTURE OF MESSAGES.

The following tables contain the part of information included in ASTM 1394 format adopted here. Host can send many fields but only those included in the present tables are processed.
Header record (level 0)

TABLE 6

Field name	ASTM ID	Host	Inst.	Comment
Record type ID	1	X	X	Always H. Starts every message. No delimiter between first and second field
Delimiter definition	2	X	X	Field, repeat and escape delimiters
Sender name or ID	5		X	Instrument ID Software version 1.0
Version No.	13			1394-97
Date and time of message	14		(X)	From YYYYMMDDHHMMSS.

Message terminator record (level 0)

Field name	ASTM ID	Host	Inst.	Comment
Record type ID	1	X	X	Always L. Ends every message. No delimiter between first and second field
Sequence Number	2	X	X	Always 1. One terminator per message.
Termination code	3	(X)	(X)	N or missing: normal termination E: unknown error I: no information available from last query

TABLE 7

Patient information record (level 1)

Field name	ASTM ID.	Host	Inst.	Comment
Record type ID	1	X	X	Always P
Sequence number	2	X	X	Running number within message. Starts with 1
Practice assigned. Patient ID	3	(X)	(X)	Patient ID. NULL patient is allowed.
Patient Name	6	(X)	(X)	Patient Name. The whole name should be given here as a string of up to 30 characters. All others will be ignored
Birth date	8	(X)		
Physician ID	14	X	X	Doctor. 30 characters.
Patient known or suspected diagnosis	19	X		Diagnostic. 10 characters.
Location	26	X	X	Section ^ Bed

TABLE 8

Test order record (level 2)

TABLE 9

Field name	ASTM ID	Host	Inst.	Comment
Record type ID	1	X	X	Always O
Sequence number	2	X	X	Running number within patient information. Starts with 1
Specimen ID	3	(X)	(X)	Sample protocol. If omitted, blank will be used.
Instrument specimen ID	4		(X)	Internal correlative number used by instrument.
Universal Test ID	5	(X)	(X)	^^^Test ID. Will accept only those identifiers as defined in the table of methods. Host MUST use these identifiers. Multiple ID, separated by identifier, is admitted.
Specimen collection date	6	X		Structure YYYYMMDDHHMMSS
Specimen descriptor	8	X		Type 1: Serum, 2: plasma, 3: urine, 4:CSF, 5:other

Result record (level 3)

TABLE 10

Field name	ASTM ID	Host	Inst.	Comment
Record type ID	1		X	Always R
Sequence number	2		X	Running number within test order. Starts with 1
Universal test ID	3		X	^^^Test code as defined in the Table of Methods in the instrument
Data or Result	4		(X)	If result is not “Done”, no entry will be available in the Historic Table, from where data are retrieved.
Units	5		X	Units as defined in the Table of Methods.
Result range flags	7		X	N: Normal A: Abnormal
Result status	9		X	P: Preliminary F: Final X: Cancelled P: Pending
Date/Time test is completed	13	(X)	(X)	Structure YYYYMMDDHHMMSS. No value if test is not completed.
Instrument identification	14		X	Instrument ID as defined in the Translator entry that corresponds to “HumaStar 600”

Request information record (level 1)

TABLE 11

Field name	ASTM ID	Host	Inst.	Comment
Record type ID	1	X		Coded as Q.
Sequence number	2	X		Always 1
Starting Range ID	3			Patient ID Sample ID, or all
Universal test ID	5	(X)		^^^Method ID or all
Beginning Request Results, Date and time	7	(X)		Structure YYYYMMDDHHMMSS.
Ending request of results, Date and time.	8	(X)		Structure YYYYMMDDHHMMSS.

5.8.1.1 Field lengths used by instrument

TABLE 12

Field	Length in characters
Instrument ID	0
Software version	9
Date and time of message	14
Patient ID	30
Patient name	30
Date of birth	8
Patient sex	1
Specimen ID	30
Instrument specimen ID	30
Test ID	0
Specimen collection date and time	14
Clinical information	100
Section ID	30
Data of measurement	8
Units	8
Reference ranges	Low 6, High 6
Data/time test completed	14
Date/time beginning request	14
Date/time ending request	14

5.8.2 COMMUNICATION EXAMPLES

Software request of simple data and results.

Rx: {ENQ}
Tx: {ACK}
Rx: {STX}1H|\^&|{CR}{ETX}61{CR}{LF}
Tx: {ACK}
Rx: {STX}2Q|1|^Pepe||ALL||||||||O{CR}{ETX}A4{CR}{LF}
Tx: {ACK}
Rx: {STX}3L|1|N{CR}{ETX}06{CR}{LF}
Tx: {ACK}
Rx: {EOT}

Host request of performed analysis.

Tx: {ENQ}
Rx: {ACK}
Tx: {STX}1H|\^&|{CR}{ETX}61{CR}{LF}
Rx: {ACK}
Tx: {STX}2P|1|86|||Maxwell Smart||19780523|M||||Cureta|||||Nada|||||||Piso 3^Cama 1{CR}{ETX}A9{CR}{LF}
Rx: {ACK}
Tx: {STX}3O|1|12345||^^^COL\^^^GLU|||20010506||||A||||Raro Color|||||||||Q{CR}{ETX}07{CR}{LF}
Rx: {ACK}
Tx: {STX}4P|2|99|||La 99||19780523|M||||Cureta|||||Algo|||||||Piso 3^Cama 2{CR}{ETX}FE{CR}{LF}
Rx: {ACK}
Tx: {STX}5O|1|12346||^^^GLU|||20010506||||A||||Feo Color|||||||||Q{CR}{ETX}3C{CR}{LF}
Rx: {ACK}
Tx: {STX}6O|2|12346||^^^COL|||20010507||||A||||Extraño Color|||||||||Q{CR}{ETX}7F{CR}{LF}
Rx: {ACK}
Tx: {STX}7P|3|007|||James Bond||19440101|M||||Cureta|||||Algo|||||||Piso 3^Cama 3{CR}{ETX}6D{CR}{LF}
Rx: {ACK}
Tx: {STX}0O|1|12347||^^^COL\^^^GLU|||20010506||||A||||Raro Color|||||||||Q{CR}{ETX}06{CR}{LF}
Rx: {ACK}
Tx: {STX}1L|1|c{CR}{ETX}19{CR}{LF}

Rx: {ACK}
Tx: {EOT}

Host request and software answer of results.

Tx: {ENQ}
Rx: {ACK}
Tx: {STX}1H|\^&|{CR}{ETX}61{CR}{LF}
Rx: {ACK}
Tx: {STX}2Q|1|ALL||ALL||20030916120000|20030916120000{CR}{ETX}4A{CR}
{LF}
Rx: {ACK}
Tx: {STX}3L|1|c{CR}{ETX}1B{CR}{LF}
Rx: {ACK}

Tx: {EOT}
Rx: {ENQ}
Tx: {ACK}
Rx: {STX}1H|\^&|{CR}{ETX}61{CR}{LF}
Tx: {ACK}
Rx: {STX}2L|1|I{CR}{ETX}00{CR}{LF}
Tx: {ACK}
Rx: {EOT}

5.9 Definition and use of sample profiles

Sample profiles are useful for ordering predefined patterns of tests.

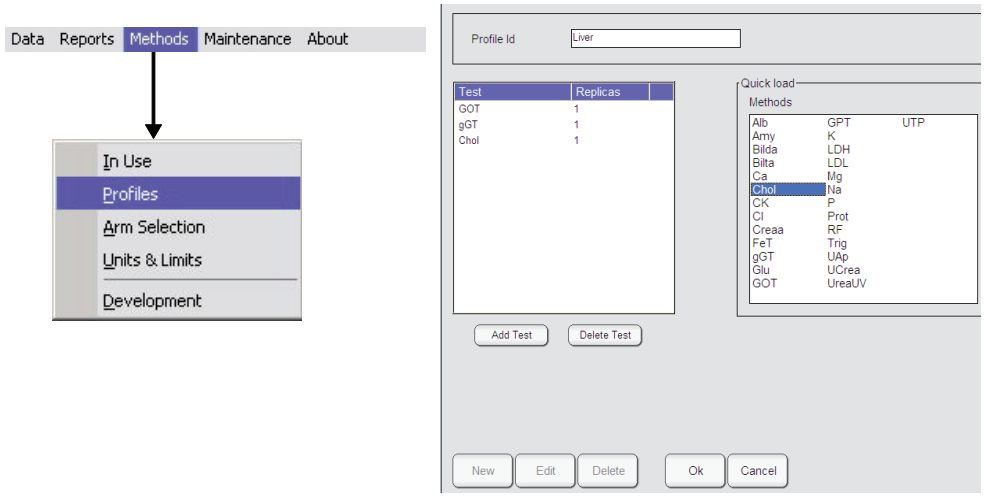
5.10 Defining a sample profile

Select in Menu ***Methods / Profiles.*** Profiles definition window is displayed. To edit the definition of a predefined sample profile, first select the sample profile from the list on the right and then press ***Edit*** .

To enter or define a new sample profile, press ***New*** .

To add a new test to the sample profile press ***Add Test*** and select or type in the method ID. Then type in the number of replicates for that method, and press ***Ok*** to add the test or ***Cancel*** to abort. To remove a method from the sample profile press ***Delete Test*** .

FIGURE 49



Repeat this operation for each required test on the profile. Then press ***Ok*** to finish or Cancel to abort.

5.10.2.1 Removing a sample profile

To remove a sample profile from the list, first select the sample profile from the list on the right and then press Delete .

Press Yes to confirm or No to abort.

6 DEFINITION OF METHODS

For open channels only!

There are four mayor types of methods or procedures in clinical chemistry analysis results. Photometric methods control the way the reactions take place. Their definitions include the volumes of reagent and sample, the times when the absorbance measurements shall be taken by the photometer and the calculations to obtain the final result. ISE methods define the ion selective electrode measurements only. Calculated and external methods are used to compute a new result with the results of other methods and/or externally added values.

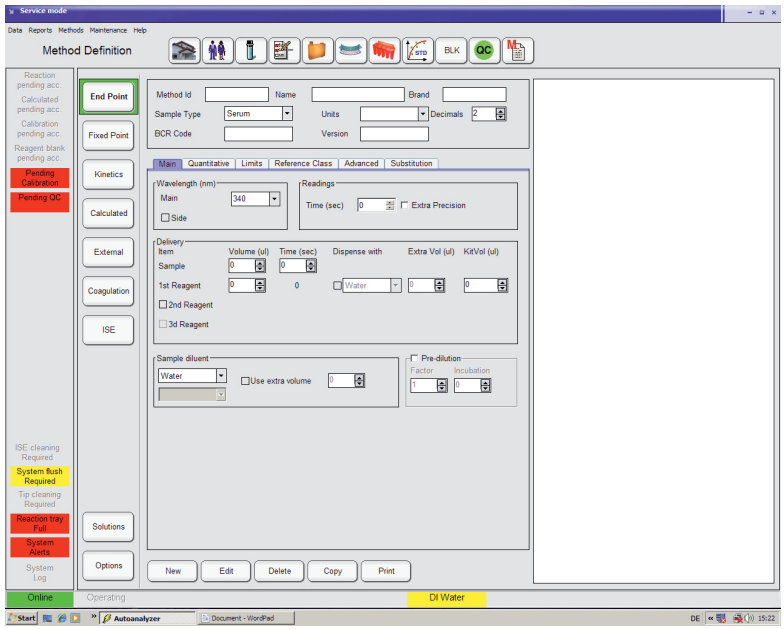
6.1 Management

To work with methods press button

The method definition window is displayed where you can choose different methods' categories and options on the left, and the corresponding methods' list on the right.

The method type defines the very general behavior of the method. Reaction or photometric types include ***End Point*** , ***Fixed Point*** and ***Kinetic*** ; definition of selective electrode measurements through ***ISE*** ; relate other methods results using a formula through ***Calculated*** ; and added ***External*** measurements.

FIGURE 50



The ***Options*** and ***Solutions*** category allow managing several lists as detailed in section 5.4.
Use ***Solutions*** to define and specify kind (cleaning or diluents) of user solutions and set the BCR code.

6.1.1 CREATING OR EDITING A METHOD

To edit a method already defined, first select the corresponding type, then select the method ID from the list on the right and finally press ***Edit*** button.

To create a new method test, first select the corresponding category, and then press ***New*** on the bottom of the screen.
Complete or modify current information as suggested in 6.2.

6.1.1.1 Erasing a method

To erase a method, first select the corresponding type, then select the method ID from the list on the right and finally press ***Delete*** button. Press ***Yes*** to confirm or ***No*** to abort.

6.2 Method parameters

Several sections can be accessed in the method definition window.

6.2.1 COMMON PARAMETERS

The **method ID** is unique. Therefore, replicates are not allowed because it univocally identifies the method. Letters (A-Z, a-z) and number digits (0-9) can be used as well as hyphen signs (- and _), however avoid using other delimiters, punctuation signs and spaces.
The Name is used in reports, while External name is intended for an external system interchange. The units indicate the measuring units of the result (quantity, concentration, activity, time, percentage, etc.). Available units can be loaded in the Options menu. The number of decimals defines the decimal representation of results. Sample type defines the nature of the sample (Serum, Plasma, Urine, CSF, Dialysis or Other).
The BCR code identifies reagent as defined by manufacturer. It could eventually coincide with the method ID.
Version allows user or reagent manufacturer to keep control of the method release version.

6.2.2 MAIN PAGE

These general parameters are applicable for all photometric/colorimetric reactions. Others are specific to the reaction type.

Wavelength. Main and dichromatic reference. They are shown in drop down menus. Values are taken from the information stored in the instrument itself, according to the installed filter set.

Volumes. Up to three reagents can be programmed. If more than one reagent is programmed, dispensing times can be added, all defined after sample delivery.

Time. Indicates delay after the addition of the first reagent. If sample delivery time is set to zero, it is delivered with the **first reagent.** For a 2-regent method, both reagents can be delivered together (second reagent time equal zero) or at different times. When sample is delayed, system will take reagent already delivered and next aspirate sample. This way, all samples will be washed away by reagent.

It is possible then, to pre-incubate reagents in the tray and then start the reaction by the addition of sample.

Readings. Reading time is counted after the addition of the last fluid (reagent or sample). In the case of kinetics, incubation starts with the addition of last fluid and reaction time after the incubation.

Dispense with .Extra volume. Each reagent can be aspirated either with additional reagent or with water. The extra reagent is discarded, its use is recommended when water carryover must be avoided. An extra volume of 10 to 15% can be useful. If extra water is used, this incorporates some water to the reaction. It is used when additional water does not interfere in the reaction but will guarantee that water carryover is similar in all samples.

Sample Diluents. Sample will be pre-diluted in two different situations: if programmed in method or if result is above some specified limits. In both cases, user must define in advance how dilution will be processed. There are several possibilities: a) washing water, b) Reagent, c) Specific diluents. If reagent option is chosen, drop down menu will include all reagents in method (1, 2 or 3). If Specific diluents option is used, menu will include all entries included in the Solutions as diluents:

Pre-dilution. Specific methods, mainly turbidimetric, require sample dilution in one of the above specified forms. Dilution is understood as **1 in the factor value**. That is, a factor of 20 means one part of sample and 19 parts of diluents.

6.2.2.1 Specific data

End point

Readings. Measuring time starting when last reagent was added if more than one or when sample was added if only one reagent is present. When **Extra Precision** is used (recommended), two consecutive readings are averaged.

Fixed Point

Readings. Incubation is the time interval between addition of last reagent and the first reading. **Reaction time** is the time interval between two readings. When **Extra Precision** is used (recommended), each value is the linear interpolation of two readings, one before and one after the specified time.

Kinetics

Readings. Incubation is the time interval between addition of last reagent and the first reading. **Reaction time** is the time interval in which 10 readings are performed. These 10 readings define the slope for the concentration calculation (in some cases, only 9 points are considered; See Section 11.1.4.

6.2.3 QUANTITATIVE

In **Calibration type** we have two options: fixed **Factor** methods where factor is provided by manufacturer fwww.windguru.cz/es/or a given temperature or **Curve/Linear** where operator uses one or more standards for calibration. The definition of a calibration curve is made in calibration screen, ***Calibrator Setting > Add Test option.*** The **Fixed point** option determines the number of points used in calibration. If this option is not selected, the system can use all points or less and can produce a non sense result.

If this option is not selected, the user can define a calibrator set with any number of points.

The **Mandatory Formula** defines the type of calibration and it cannot be modified in the acceptance screen.

Calibration can be also taken from another method by selecting **Use from this method** and selecting a desired one from listing in the pull down menu. This feature is useful, for instance, to measure serum and urine with the same calibration. Respective pre-dilution factors are taken into account in each case.

The **Validity time** will indicate when calibration must be renewed, unless lot is modified. Samples will be pending of calibration until new calibration is performed. Blanks are also erased. A 0 value will leave this option unused.

Unit conversion. Includes a bias and a factor (linear transformation parameters) required to transform units between different systems.
Direction. Ascending or descending according to method. If Direction check is enabled, flagged results will require manual acceptance.

Blank. All methods have an option for measurement of a reagent blank. If method uses more than one reagent, blanking is made with a reagent mixture similar to those used in method. For better accuracy, sample is replaced with a Specific Diluent, taken from the ***Solutions*** (see 6.3) or with Reagent.
In both cases the **Extra Volume** option is available.

The number of **replicates** can be defined in the screen of blanks but can also be included here as part of the method. Its default value is 1.

Blanks have a **Validity time** defined in the method. New blank will be requested if Validity time is expired or if reagent lot number if modified. In fact, the instrument will store a different blank for each reagent lot number in use. The blank can be **automatically performed** when the reagent bottle in use is substituted without operator's action with another already in the tray (See 5.5).

For End Point methods, the **Reagent and Cuvette Blank** can be applied. In this case, reagent is delivered in the reaction cuvette, measured, sipped again and delivered in the same cuvette together with sample and additional reagent, if required. This procedure will increase precision but will take some extra time.

6.2.4 LIMITS

Concentration Validity limits can be used to automatically rerun a reaction outside the limits. A pre-diluted sample or with Less Sample rerun can be ordered for high samples. The pre-dilution takes into account high and low limits and calculates dilution factor as to put reading in the midpoint, approximately.

Also, a **More Sample** choice will produce an automatic repetition with more sample in the amount required to enter into the method limits, if the Low limit is not reached. Low and high validity limits are the lowest and highest values the method can determine. Calculations are adjusted to produce true results.

Integrity check absorbance limits are used in the integrity check procedure to validate quality of reagents in use. Low and high limits can be enabled or disabled.

Concentration Duplication limits can be used to verify a result outside the stipulated limits. This limit is independent from the method reference value and can be used to define repetitions according to each laboratory needs. For instance, laboratories working for an insurance company could establish to duplicate every analysis with Glucose higher than 140 mg/dl.

6.2.5 REFERENCE CLASSES

Reference classes define the normal limits or reference values for the various types of samples: men, women, children, etc.

Reference classes can be added to the method definition using particular low and high limits. Reference classes are used for analysis flagging and reports. The reference classes are introduced in the ***Options*** (see section 6.3). To introduce an already defined reference class in the method, press the ***Add*** button.

6.2.6 ADVANCED FEATURES

Advanced features include post and pre-wash for interference control, manual or automatic acceptance of calibrations and samples, tray definition.

Tip Post-wash. Used when a highly contaminant reagent to other reagents or to the system is in use. It can be performed either with water or with a specific solution defined in ***Solutions*** (see 6.3).

Tip Pre-wash for interference. When a reagent interferes over other, a probe pre-wash can be performed using wash water or a solution defined in the ***Solutions*** (see 6.3) or the reagent itself.
This action can be performed *Always* or only *after* any of the listed interfering reagents. To define interfering reagents over the reagent under edition, press button ***Add*** and select from the list of all methods stored in memory.

Acceptance. Once samples have been processed, they can be automatically sent to the historic file or require operator's decision. This option can be programmed method by method. When test is flagged either because it is out

of some range or requires dilution, acceptance will become manual even if programmed as automatic.

Arm selection. Selection is equivalent to those that can be performed in ***Methods > Arm selection***.

Shake (mixer). Probe motor is activated when tip is immersed in the reaction cuvette. Shaking period can be adjusted to Normal, X2, X3 or suspended. Shake is performed on tip cleaning, intermediate wash, reaction cuvette and pre-dilution mixing.

On board stability. Once reagent is placed in tray or refilled, when this period is expired, reagent will be removed from tray, if the **Keep Using** option is enabled, only a warning will be issued.

Cuvette post-wash. Before new use, cuvettes used by the method can be washed with a decontaminant solution. Decontaminant solution is defined in the ***Options*** menu. The typical application is the washing with NaOH of cuvettes used with latex methods.

After sample tip wash. After sample intake, this option, if enabled, will cause that tip is washed before delivery in the reaction cuvette. This feature will improve linearity in methods with very low absorbance.

Interfering methods. Methods interfering can be including in the list. The system will prevent from delivering the interfering method immediately before or prevent from delivery in the cuvette where the interfering method was delivered in the previous tray turn.

Nevertheless, it is strongly recommended to program interfering methods in different arms and use this option only when several interfering situations require keeping interfering methods in the same tray.

6.2.7 CONSUMPTION

This section applies to kinetic methods only.

Consumption check. Each kinetic method requires a consumption check before measurement during the incubation period. Its purpose is to prevent from producing false negative results due to excessive initial consumption.

Consumption limit value is in general determined by manufacturer's recommendation. Method includes options on how measuring interval is defined.
If *First and second point* option is selected, evaluation is performed when measuring starts and between two first measuring points out of 10 readings performed in every kinetic measurement. In the *Time and first point option*, measurement is *before* measurement sequence. Interval is defined in *Time before first*. Second option is recommended with 15 seconds for incubations below 60 seconds and 30 seconds for incubations above 60 seconds.

Behavior. With conservative behavior, instrument will perform 10 readings evenly spaced along the *Reaction Time*. In the adapted option, instrument will "learn" from the read values in the incubation period and will stretch or enlarge measuring period and intervals, optimizing precision in the analysis if consumption is low by increase of total reaction time and interval between readings. If consumption rate is high, total reading interval will be shortened to preserve linearity. This second option is recommended.

Initial absorbance limit. In case that consumption is so high that all substrate is consumed before the first reading, criteria based on initial absorbance limit can be applied. If absorbance is *below* limit in descending reactions or above limit in ascending reactions, sample will be pre-diluted.
Examples: if ALT kinetic assay produces a value below 0,600, this means that absorbance diminished from about 1,300 to less than 0,600 in the incubation period.
If ALP first reading is above 0,800 all substrate has been consumed in the incubation period. Both examples require that reagent alone has passed integrity check before.
It is recommended to follow reagent manufacturer directions at all times.

6.2.8 REAGENT SUBSTITUTION

If two or more methods have to share some reagent, it is convenient its substitution with a diluent. Example: IgA and IgM methods of the same brand share the same buffer; first define the Turbidimetric Buffer as Diluent (Use ***Method Definition > Solutions > New > Diluent***) ; next, introduce in IgA and IgM methods, in the substitution page the "Turbidimetric Buffer" and check "1st Reagent".

6.2.9 QUANTITATIVE

Conversion of units

- Factor
- Bias

The factor-bias method is equivalent to the slope-intercept method and affects the final result by multiplying all data with a factor (slope) or adding a constant value (bias or intercept). This system allows expressing data in different units or comparing results with other instruments.

The bias correction allows coinciding data from turbidimetry and viscosity methods

Base Line

Minimum: When this item is enabled, threshold is measured from the minimum measured absorbance. If not enabled, reference is set to the initial absorbance (First point). This feature is useful because some reagents reduce turbidity after few seconds.

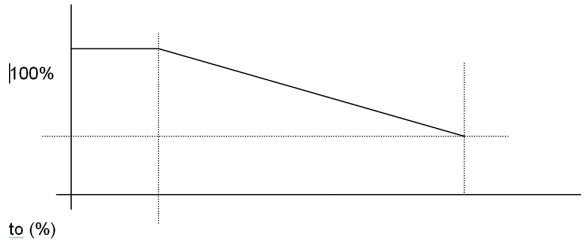
Variable threshold

Threshold can be variable with time, starting at a given initial value and linearly reducing its value to a given percent of original threshold.

From (sec.): Initial time from which threshold can linearly decrease with time.

To: (% of threshold): This parameter indicates the % of initial threshold when the wait time expires. If no variable threshold is desired, this parameter should be set to 100%.

FIGURE 51



Calibration type

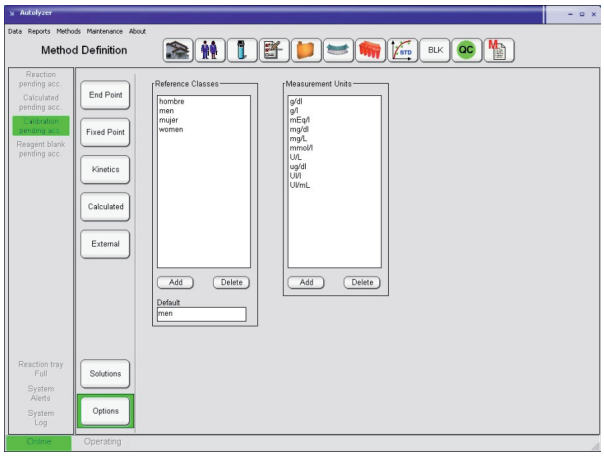
With fixed factor in1, data can be measured in seconds.

Calibration curve in coagulation must be set in percent of Normal sample, pool or control. It is useful to establish dilutions, which represent some points between 100% and 10%. The number of dilutions can be up to 10 but normally with 4 points is enough to define a coagulation curve.

It is useful also to utilize automatic dilution feature. By using a dilution ratio of 2, 4 points and inclusion of 100% (0 should not be included), the curve will be built with 100%, 50%, 25% and 12.5%. Sigmoid, logit or linear equations will result. Selection of equation with best fit (minimum least squares summation) is mandatory.

6.3 Accessories: Solution and Options

FIGURE 52



There are two important data sets that are introduced as ***Options*** :
Measurement units: units can be defined by operator but usually most used units are already factory defined.

Reference classes: listing of all categories for which normal reference values can be defined (male, female, child, etc.). Be sure to define categories in your own language.

To add new components, press ***Add*** in the corresponding set, write category and then press ***Ok*** to confirm or ***Cancel*** to abort.

To remove components, simply click on them and press ***Delete*** . No confirmation is required. Nevertheless, when clicking on component, a window asking ***Set as default?*** will display. If answer is No, you can proceed to delete it.

If your answer is Yes, you can re-define component as default.
In Solutions there are two categories Fixed in the system and user defined.

The **Fixed Solutions** are those for probe wash and rinsing, ISE cleaning and ISE urine dilution. They cannot be deleted or modified but require operator's action for placing in the tray. Barcodes can be attached to them.
Cleaning solutions: additional cleaning solutions for several methods.
Diluents: generic and specific diluents required in some methods (physiological solution, distilled water, etc.).
To add components, press ***Add*** button, define category and barcode identifier, if any. To confirm, press ***Ok*** or ***Cancel*** to abort.

6.4 Calculated methods

Method ID, name, units, decimals, and external name are introduced as in any other method.

Formulae are calculated with methods previously stored in the memory.
The ***Add*** button allows introducing methods in the formula bar. Methods IDs, used as variables, are linked with common mathematical operators: +, - , * / , (), etc. Button ***Test Formula*** will check the formula's consistency.

Methods show formula surrounded by symbols > and <.
Example: <CHOL>/<HDL>
External methods can be used in formula if previously stored in memory.
Methods may correspond to different samples if samples are assigned to the same patient. Reference classes are defined in the method screen and have no relation to categories defined in the Options.

6.5 ISE Methods

See section 0 for details.

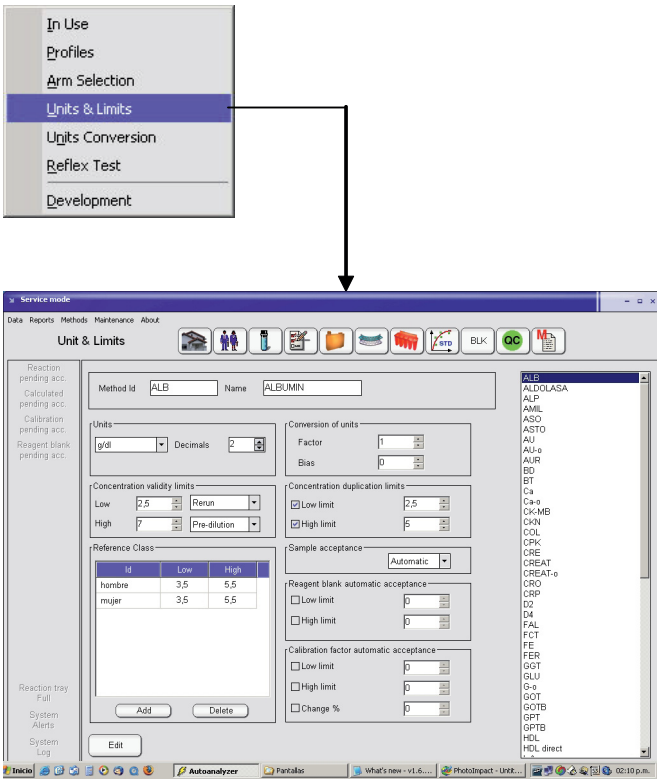
6.6 External Methods

External methods are printed out together with those calculated by the instrument.
They are useful for the introduction of constants in the calculated methods. Such constants are, for instance "Creatinine clearance", "24-hour volume", etc.
Method ID, name, units, decimals, external names are introduced as usual.
Reference classes are defined in the method screen and have no relation to categories defined in the Options.

6.7 Units and Limits

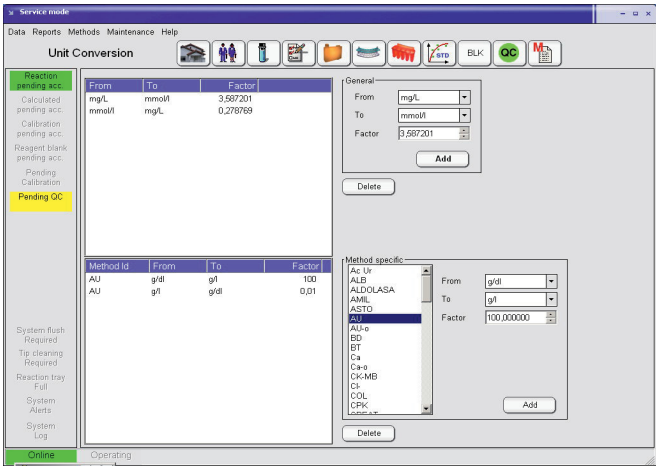
Units and limits can be modified from the menu of methods without direct access to a given method in particular. This feature is very useful when operating in closed systems.

FIGURE 53



6.8 Units conversion (for service only)

FIGURE 54



Units Conversion

TABLE 13

From	To	Factor	From	To	Factor
µg/l	ng/ml	1	µkat/l	U/L	60
µmol/ls	U/L	60	g/dl	g/l	10
g/l	g/dl	0,1	g/l	mg/dl	100
mg/dl	g/l	0,01	mg/dl	mg/l	10
mg/l	mg/dl	0,1	mmol/l	mval/l	1
mval/l	mmol/l	1	ng/ml	µg/l	1
U/L	µkat/l	0,016667	U/L	µmol/ls	0,016667

TABLE 14

Method Id	From	To	Factor	Method Id	From	To	Factor
Bilda	µmol/l	mg/dl	0,058469	Bilda	mg/dl	µmol/l	17,10308
Bilta	µmol/l	mg/dl	0,058469	Bilta	mg/dl	µmol/l	17,10308
Ca	mg/dl	mmol/l	0,249	Ca	mmol/l	mg/dl	4,016064
Chol	mg/dl	mmol/l	0,02586	Chol	mmol/l	mg/dl	38,66976
Cl	mg/dl	mmol/l	0,282	Cl	mmol/l	mg/dl	3,546099
Creaa	µmol/l	mg/dl	0,011312	Creaa	mg/dl	µmol/l	88,401697
FeT	µg/dl	µmol/l	0,179	FeT	µmol/l	µg/dl	5,586592
Glu	mg/dl	mmol/l	0,0555	Glu	mmol/l	mg/dl	18,018018
HDL	mg/dl	mmol/l	0,02586	HDL	mmol/l	mg/dl	38,66976
K	mg/dl	mmol/l	0,256	K	mmol/l	mg/dl	3,90625
LDL	mg/dl	mmol/l	0,02586	LDL	mmol/l	mg/dl	38,66976
Mg	mg/dl	mmol/l	0,411	Mg	mmol/l	mg/dl	2,43309
Na	mg/dl	mmol/l	0,435	Na	mmol/l	mg/dl	2,298851
P	mg/dl	mmol/l	0,3229	P	mmol/l	mg/dl	3,096934
Trig	mg/dl	mmol/l	0,01143	Trig	mmol/l	mg/dl	87,489064
UAp	µmol/l	mg/dl	0,016811	UAp	mg/dl	µmol/l	59,484861
UreaUV	mg/dl	mmol/l	0,1665	UreaUV	mmol/l	mg/dl	6,006006

This conversion table can be reached by

Methods > Units conversion

The software will automatically calculate new values when user changes units in the method. Table contains Method, unit A, unit B and factor.
To put the change into effect, select:

Methods > Units and Limits

and press button Change Units. The button is visible if at least one conversion is defined.

The change will include:

Calibration factor, redefined.
Concentration validity limits
Concentration duplication limits.
Factor of automatic acceptance
Reference classes
Calibrator sets
Control sets.

The table of conversion can be imported through

Data > Import > Units Conversion

A report is generated with the conversion table. The access is

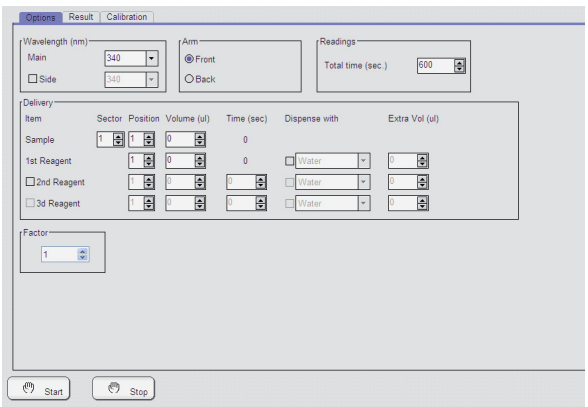
Reports > Units conversion

6.9 Developement of a Method

The option ***Methods > Development*** gives access to review in real time any reaction. This method does not run with others as part of the automatic cycle. It is used alone, sample by sample and its purpose is to study slope, end point, optimum range, incubation period, etc.

In **Options**, basic method parameters are defined: wavelengths, number of reagents, volumes, total measuring time. In Calibration page, analysis type is defined and fit formula calculated. In Results, Time 1 and Time 2 can be adjusted and then review results when time limits are modified. This way, method parameters can be optimized.

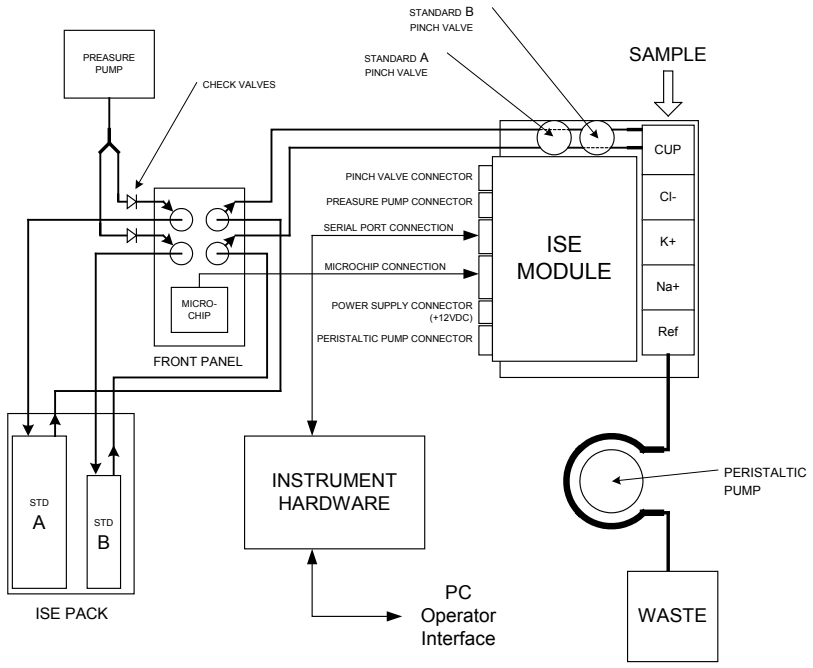
FIGURE 55



7 ISE MODULE CAT.-NO. 16663

7.1 Overview

FIGURE 56



When module is turned on, bottles containing Standard A and B in the pack are pressurized. Upon system demand, Standard A and B are delivered to electrodes for rinse, one point or two point calibrations.

One point calibration is performed *at the end of every sample*. Two-point every 8 Hs if the module is still on. Calibrations do not require operator's action.

After daily operation, cleaning action must be executed. Operator must place cleaning solution in defined position in the reagent tray and the cleaning action will be automatic.

Other actions, such as wetting of electrodes with Standard A when system is inactive for more than 15 minutes are also automatically performed.

All actions can also be performed from the Manual parameter setting menu. (See section 7.6.1).

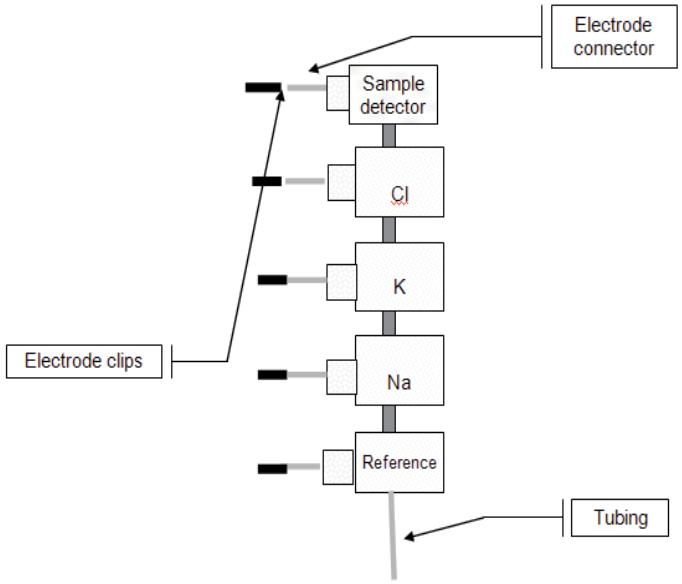
For automatic operation, all the actions defining methods, samples, profiles, methods in use, etc. are similar to those executed for chemistry methods.

No reagents are required in tray, except for cleaning solution and urine diluents.

Module always measures all installed electrolytes; operator can request all data or only those electrolytes he is interested in.

Waste system is common to the rest of the instrument and does not require additional handling care.

FIGURE 57



7.2 Principles of measurement

ISE module operates with direct measurement of electrolytes through membrane ion selective electrodes.

Electrodes operate upon selective electrolyte detection *properties* of membrane electrolyte filled sensors.

A potential is developed, referred to the reference electrode, at the ion selective membrane.

(This is done by means of the Ion selective membrane which develops a potential with respect to reference electrode.)

Potential satisfies the Nernst equation:

$\mathbf{E = E^{o} \pm (RT/nF) \ln a_i}$ The sign is: + for cations and − for anions

But $a_i = f_i c_i$

$\mathbf{E = E^{o} \pm (RT/nF) \ln (f_i c_i)}$

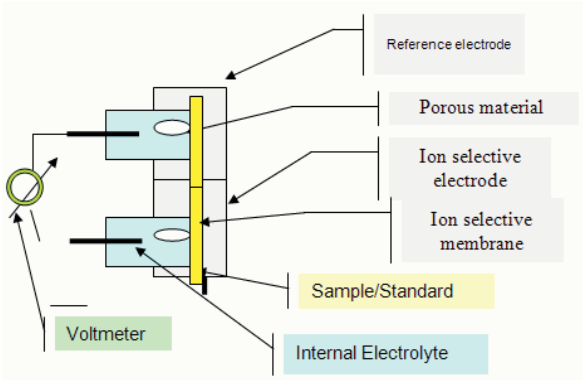


FIGURE 58

Where:
E = Measured electrical potential
Eº = Electrical potential constant, which depends on the measuring system.
Ai = Activity of measured ion/ions
R = Constant of ideal gases.
T = Temperature, (absolute)
n = Oxidation number of exchanged electrons in the reaction.
F = Faraday constant
c_i = Concentration of measured ions
f_i = Activity coefficient of measured ions.

The equation, in terms of instrument parameters is:

$$E = E^{\circ} \pm P \log (f_i c_i)$$

Where:
P = Slope of Calibration curve for a given ion and working temperature.
Slope is determined measuring Standards A and B of known concentrations.

$$E\ (sample) = E^{\circ} + P\ Log\ (f_i c_i\ sample)$$

$$E\ (Standard) = E^{\circ} + P\ Log\ (f_i c_i\ standard)$$

$$\Delta E = E_{sample} - E_{Standard} = P \log (c_i\ sample - c_i\ standard)$$

Then, the equation which determines concentration is

$$Ci_{sample} = ci_{standard}\ 10^{(\Delta E/P)}$$

This is the algorithm used by ISE module.

7.3 Technical Specifications

Module is factory installed only.

- Capacity for 3 simultaneous electrodes: Sodium, Potassium, Chloride. Others available upon request. Fully random access with other chemistry methods, over same or different samples.
- Samples are processed with higher priority than coagulation and chemistry.
- Fully STAT capabilities at all times.
- Control samples can be measured, stored in History file and Quality Control data obtained.
- Automatic calibration in one or two points.
- All readings are in mmol/l units. Unit can be transformed with slope/intercept feature in each method.
- Throughput of 100 serum samples/hour, equivalent to 300 readings/hour for three installed electrodes.
- Sample volume: 125 µl for serum, 20 µl for urine. This volume allows determining 3 electrolytes.
- Maintenance is automatically performed or flagged by system.

TABLE 15

	Sodium	Potassium	Chloride
Measuring linear range in serum [mmol/L]	40 - 220	1 – 30	20 - 250
Measuring linear range in urine [mmol/L]	20 – 300	2 – 300	20 – 300
Sensitivity [mmol/L]	0,1	0,01	0,1
Precision (serum)	C.V<= 2% 140/160 mmol/L	C.V<= 2% 4/8 mmol/L	C.V<= 2% 90/125 mmol/L
Precision (urine)	C.V.<=10%	C.V<=5%	C.V<=5%
Typical electrode usage time	9 months	9 months	9 months

7.4 Reagents (ISE pack)

ISE reagent pack (16660/14) contains the following elements:

STD-A	Standard A solution: 500 ml	
STD-B	Standard B solution: 100 ml	
CHIP	Microchip with coded information and data	
I-CLEAN	Wash solution: 20 ml	(16660/11, 6 x 20 ml)
I-DIL	Urine diluent: 20 ml	(16660/12, 6 x 20 ml)
I-COND	Sodium Conditioner: 20 ml	(16660/13, 4 x 20 ml)

FIGURE 59

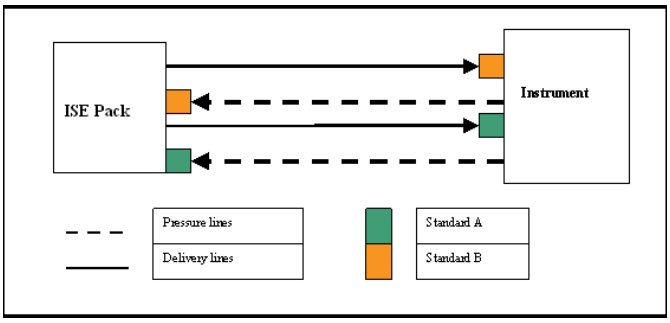


FIGURE 60

7.4.1 COMPOSITION

Item	Volume	Composition	Comments
ISE Standard Pack			
Standard A STD-A	500 ml	Na^+ = 140 mmol/l K^+ = 4.0 mmol/l Cl^- = 125 mmol/l Ca^{++} = 1.0 mmol/l Li^+ = 1.0 mmol/l Preservative	Compositions are fixed and cannot be modified by user. They can differ from lot to lot. Values are recorded in microchip and don't need to be updated by operator. **Do not attempt to use a reagent lot with microchip corresponding to another lot!**
Standard B STD-B	100 ml	Na^+ = 35 mmol/l K^+ = 16.0 mmol/l Cl^- = 41 mmol/l Ca^{++} = 2.0 mmol/l Li^+ = 0.4 mmol/l Preservative	**Do not attempt to use a reagent lot with microchip corresponding to another lot!**

TABLE 16

Microchip CHIP	1	Electronic circuit	It contains information of concentrations of standards, calibrations, manufacturing and expiraton date, type of pack, and additional technical data required by instrument.
ISE Cleaner I-CLEAN	6 x 20 ml	0.55 % Sodium Hypochlorite	Reagent is stored in a standard inner reagent vial and fits into reagent positions 1 to 24. Once pack cover is opened, remove vial and install in selected position.
ISE Conditioner I-COND	6 x 20 ml	0.6 % Ammonium bifluoride	Reagent is stored in a standard inner reagent vial and fits into reagent positions 1 to 24.
ISE Urine diluent I-DIL	4 x 20 ml	Mg ++ = 16 mmol/l Preservative	Reagent is stored in a standard inner reagent vial and fits into reagent positions 1 to 24. Once pack cover is opened, remove vial and install in selected position.

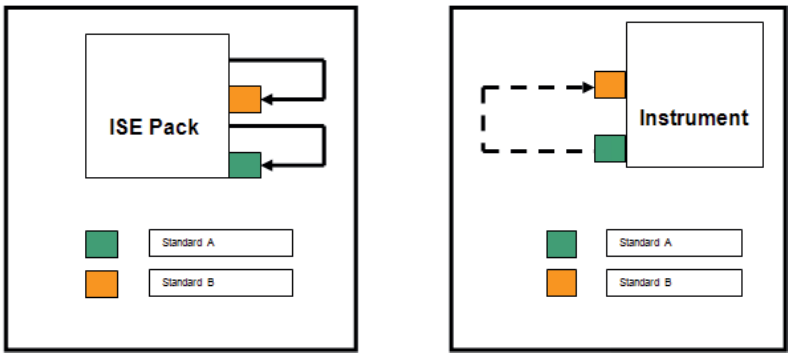
7.4.2 REAGENT INSTALLATION

! If pressure line is connected to pack before connecting to instrument and instrument is ON, liquid will be delivered and spilled.

Before installation of a new pack, please refer to Section 0 for removal of used pack. Open rear door where ISE pack must be located.

Remove pack cover. Also remove **Cleaning solution** and **Urine diluents** vials. These two solutions fit into reagent tray in positions as reported in Functional Parameters. Standard A (green coded) and Standard B (orange coded) have connectors which attach to instrument with female luer-lock terminals. In turn, pressure lines from instrument attach to luer-lock connectors in pack.

When pack is opened, delivery lines are attached to pressure connectors, each one to its corresponding Standard.



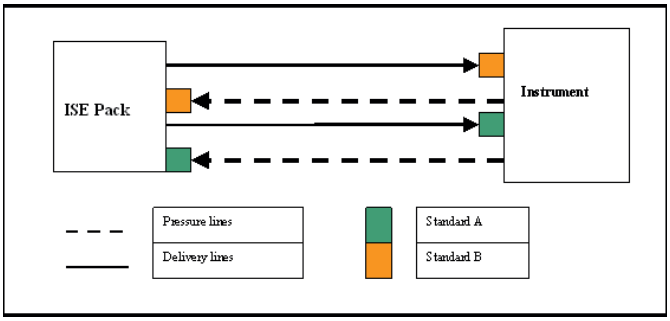
- If instrument is new and no pack was installed before, pressure lines are attached to inlet hoses. Disconnect them.
- Disconnect delivery lines in pack and connect them to instrument.

- Connect pressure lines from instrument to corresponding color coded terminals in the pack.
- Connect micro-chip to J9 connector in the instrument.

When pack is installed, be sure that absorbing sponge located below peristaltic pump is correctly positioned.

7.4.3 REMOVAL

- Disconnect pressure lines from pack.
- Disconnect delivery lines from instrument.
- If no pack will be installed immediately, attach pressure lines from instrument to inlets of standards in the instrument. This will prevent dust and contaminants from entering the delivery lines. Also, if module is turned on, any remaining liquid in the system will be eliminated through the drain circuit.
- When pack is removed, discard according to your local regulations.



! Always disconnect pressure lines from pack before disconnecting delivery lines from instrument. This will avoid any pressure in pack vials that may cause spillage through delivery lines.

FIGURE 61

! Damage in the peristaltic pump tubing may cause spillage of corrosive liquids and instrument damage. Replace tubing when instrument warns that safe number of cycles has expired.

7.5 Methods

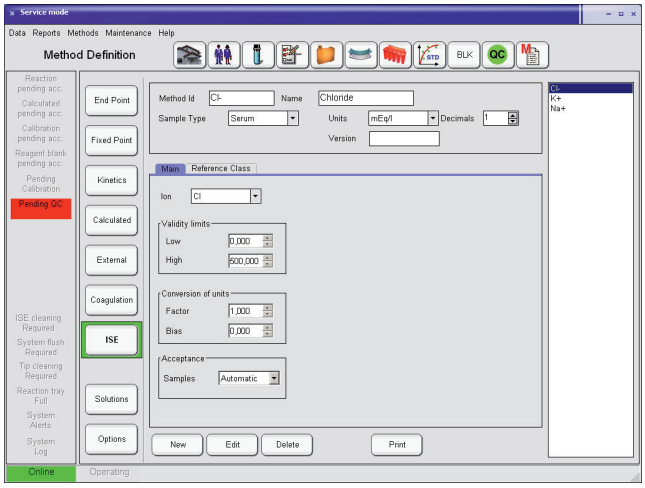


FIGURE 62

Identification: (Test ID, Name, Units): Similar to chemistry methods. Units must be mmol/l. (Verify in ***Options*** that this unit is set) .For conversion to other units, use Bias equal to zero and corresponding factor in the **Correction** section in this page.
Ion: **any of the installed ions as defined in ISE parameters**.

Sample Type: **refers to the type of sample** (serum, urine, etc.)

Reference Class: Normal expected values

7.6 Operation

7.6.1 MANUAL OPERATION

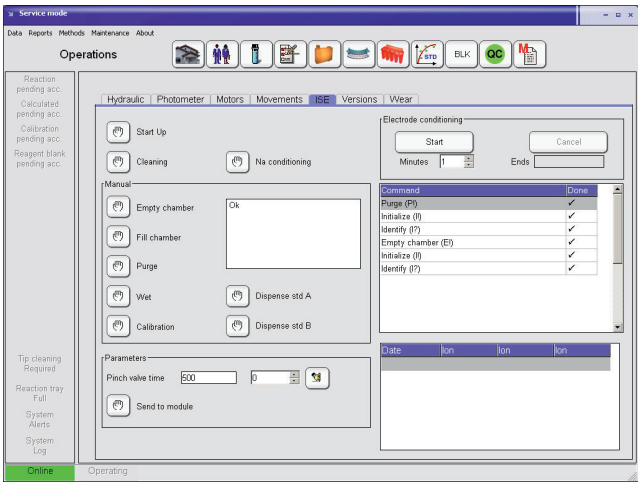
Manual operation is only recommended for test purposes. No sample determinations are made using this screen.
To access select

Maintenance > Operations > ISE

When new pack is installed purging should be automatic. Nevertheless, if purge is incomplete or missing, use this option for **purge** operation. Also, use it when a maintenance cleaning of system is performed.

Startup and cleaning are automatically performed when required.
Nevertheless, use this option when additional cleaning or calibration is necessary.

FIGURE 63



Electrode conditioning options allows leaving the system be loaded with a sample for a period that can be adjusted from one minute to several hours. Sample is taken from the **prime** reservoir. (See 4.3.2 and 8.2.1)

7.6.2 AUTOMATIC OPERATION

7.6.2.1 Serum

Serum samples are used undiluted and placed in sample vials together with other samples. Analysis can be performed either for electrolytes only or mixed with any chemistry method.
ISE methods can be programmed as samples, controls, STATS, etc.
System will give to ISE samples higher priority than chemistry methods but lower than coagulation.
Results, printouts, etc. are performed as usual and no separation of ISE from other methods whatsoever.

Priming
It is recommended the use of one or more extra dummy sample as the first serum ISE sample. This will help to stabilize results when batch operation is performed.

The priming operation is controlled by **Use Parameters** *(**Maintenance > Parameters > Use**)* where the prime operation is enabled (green) or disabled (red). Priming should not be confused with pre wash. Priming is one or more extra samples per lot or if instrument has been inactive for a given time.

7.6.2.2 Urine

Urine samples are automatically diluted by system, according to the dilution ratio specified in ISE parameters.
Urine diluent is provided in the ISE pack.
Diluent is provided in a 20-ml reagent vial that fits only in reagent positions 1 to 24. For definition of diluent in the reagent tray, first open selected position and enable it as ***split***.
It is recommended to use at least two extra dummy samples at the beginning of a batch. This will help to stabilize electrodes and improve precision.
Also, it is recommended to use of pre-wash. For setting, see Section 4.2.6.2.
Conditioning. Never use urine samples separately. You must use serum samples after a urine batch. Electrodes, mainly Potassium, improve their efficiency

with serum samples and become unstable with an excess of aqueous or urine samples.
If an important number of urine samples must be measured, consider the use of a serum sample and leave it in contact with electrodes for about 15 minutes.

7.7 Maintenance operations

Please refer to section 8, Maintenance chapter.

7.8 Errors

TABLE 17
Error Listing for ISE Module

ERROR	ION	DESCRIPTIÓN	CORRECTIVE ACTION
Kit not installed	Any	No startup	Install a valid kit
Kit expired	Any	No startup	Replace ISE pack
Empty kit	Any	No startup	Replace ISE pack
Invalid kit	Any	No startup	Utilize ISE pack designed for your instrument and/or country.
Error in filling	Any	No data acquired or calibration performed	**Inspect pump tubing, remove from pump and rub with fingers.** When repeated, ISE module operation is aborted. Check for valves, inlet tubing and pressure in pack bottles,
Error in emptying	Any	No access to the following sample or no calibration	Inspect peristaltic pump and tubing. Check leaks and kinks in tubing and electrodes.
Na unstable (*)	Sodium	No stable plateau reached in samples and calibration. Slope out of the allowed range	Electrode deteriorated. Erroneous slope after a calibration. Some samples can display this message. Only check if it persists for many samples. **Clean electrodes with Sodium conditioning solution.**

K unstable (*)	Potassium	No stable plateau reached in samples and calibration. Slope out of the allowed range	Electrode deteriorated. Erroneous threshold in module. Some samples can display this message. Only check if it persists for many samples.
Cl unstable (*)	Sodium	No stable plateau reached in samples and calibration. Slope out of the allowed range	Electrode deteriorated. Erroneous threshold in module. Some samples can display this message. Only check if it persists for many samples.
Timeout	------	Erroneous date or module miss-connection.	Communication interrupted. Instrument off.

(*) Check for slope on calibration. They should be higher than 30. Leave a serum sample in contact with electrodes for at least 15 minutes. Put sample in cup, press Fill button. At the end, press Empty button. Repeat calibration. If slope still low, consider electrode replacement.

8 MAINTENANCE

8.1 Counters

It can be accessed through

Maintenance > Operations > Wear

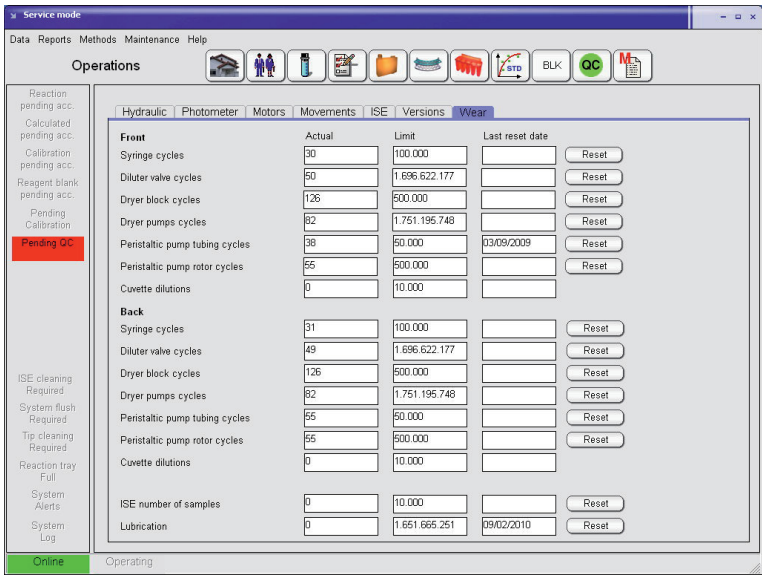


FIGURE 64

Table includes actual reading on syringes, tubing, drying blocks, pump rotors, diluter valves, dryer pumps, ISE electrodes and lubrication period. Also, latest replacement dates are shown.

When a replacement is made, reset button must be pressed and counter put to zero.

Check weekly this table and be sure to have spares for all elements.

In all cases, when instrument is reconnected or when automatic operation starts, a warning message is issued:

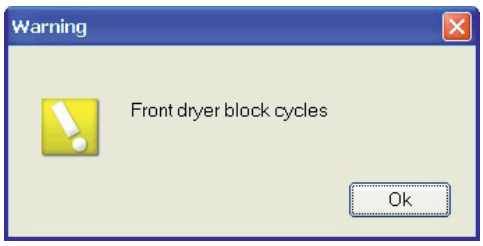


FIGURE 65

8.2 Daily care and maintenance

Recommended operations should be performed at the start of every run or on demand.

8.2.1 ISE PRIMING SERUM

For instruments having ISE option, always keep on the ISE priming position a vial having a fresh serum from a sample pool or a control.
This is to provide the necessary electrode conditioning to extend electrode useful life and ensure ISE module optimum operation.
To modify priming settings, log as supervisor and access

Maintenance > Service > Parameters > Instrumental

then choose ISE tab to enable/disable ISE priming, define the number of repetitions, and set the idle time. Replace ISE priming serum daily.

8.2.2 INSPECTION AND CLEANING OF PROBE

! Never use abrasive material: the delicate PTFE coating would be damaged.

The sample probe is a delicate part of the instrument. Precision of results is essentially dependent on how well the sample probe is maintained. Probe tip must be kept clean.

Gently remove protein deposits or solids from tip with a cotton swab soaked in Solution 1. Dry with lint-free tissue.

! Perform all automatic cleaning cycles required by the instrument.

If the probe tip is defective, remove cover of probe arm, loosen setscrew and spring that retains the needle and pull it up. Install new probe. Tighten setscrew connector fitting and cable and recalibrate the tip positions. Reset counter as indicated in 0.

8.2.3 HYDRAULIC TESTING

Purge hydraulic system from menu ***Maintenance / Operations, Hydraulic*** tab, and press ***System Flush*** (This procedure is also automatic on startup).
During process look for:

Presence of bubbles or air gaps in system

Air gaps and bubbles should be flushed, if present, during the filling operation. It is normal to find some bubbles in the peristaltic pump tubing. Repeat the process if necessary.
In case new bubbles generate in the process, determine the origin:

Come from reservoir?
Generate in pump connectors?
Generate in syringe connectors?
Are they visible only in probe tip?

Leakage in peristaltic pump
Replace pump tubing even if cycling time is not reached as shown on 8.11.1.

Constant and uniform flow from probe tip
This indicates hydraulic system is operating normally.

No droplets hanging on probe tip
When system operates normally, no droplets should be present on outer part of tip. If tip is dirty, droplets will adhere to external surface. If obstructions are present in the system, flow will be intermittent and drops will continue to fall after pump has stopped, and eventually, one will remain hanging from the tip.
When system operates normally, flow will stop instantaneously when pump stops.

8.2.4 REPLACEMENT AND CONTROL OF WASH AND CLEANING SOLUTIONS

This HumaStar 600 washes the sample probe between sample aspirations, requiring approximately 3 ml of wash solution for each performed test. The washing solution is pumped up from its reservoir and is disposed into the waste reservoir, both provided with the instrument. Both reservoirs have electronic level sensors.
If wash solution volume is not sufficient, a message will warn after initialization. It will not stop instrument operation as enough washing solution is still present. The run can be completed before refilling the reservoir. **Replace daily.**
If no refill is carried out, message reappears before next run.
Check waste container and empty, if necessary.
Control tip cleaning and rinsing solutions. Refill, if necessary.

! Never leave uncapped the cleaning solution. It will loose its cleaning power in few hours.

8.2.5 INTENSIVE CUVETTE CLEANING

Before starting every automatic cycle, the instrument will check the cuvette status. If the number of cuvettes with absorbance out of the limits defined in the ***Parameters > Use*** is greater than a pre-fixed value (usually 10), the cycle will stop.

Nevertheless, cuvettes can receive an intensive wash by selecting the operation in

Maintenance > Operations > Hydraulics > Intensive Cuvette cleaning

Operator can select volume, time of action and washing solution. This action is very useful for cuvettes used with latex type of reagents or other contaminant fluids. Perform it at the end of the working day.

8.3 Weekly maintenance routine

Proceed first with daily maintenance routine.
Empty and clean waste reservoir, including stopper and tubing.
Clean drain funnel in wash station. Use Solution 1 and rinse with water.
Clean reagent/sample tray by wiping it with mild detergent and water. Rinse with tap water and let dry. **Do not heat for drying.** If desired, dry with a towel or lint-free tissue.
Clean instrument table top with a moistened cloth. Do not use organic solvents or acids.

Refill wash solution reservoir after eliminating leftover.

8.3.1 INTENSIVE WASHER CLEANING

The washer cleaning system and pipes can be in turn cleaned with an intensive procedure located in

Maintenance > Operations > Hydraulics > Intensive washer cleaning

This procedure consist of using a suitable cleaning solution defined in the screen of cleaning solutions (See 6.3) with a volume up to 500 microliters and repeated up to 10 times (default value is 4), either back or front or both. At the end, a normal wash and drying cycle is performed.

Proceed with the daily maintenance routine.

8.4 Monthly maintenance recommendations

Proceed to the weekly maintenance routine.

8.4.1 WASHER VOLUME CALIBRATION

Following

Maintenance > Washer Volume Calibration

It is possible the testing and calibration of the washer volume. Screen will show the pump steps settings and new pump steps required for system delivery in all four wash steps. Operator can save new settings or return to default values. Target is that all deliveries are between 500 and 700 microliters.

It is recommended the use of this test at least once a week.

8.4.2 OTHER TASKS

- Perform a full photometer calibration
- Empty and clean washing solution reservoir.
- Perform an intensive washer cleaning

8.5 Maintenance on demand

Must be performed when instrument indicates the need of corrective action, or when operation anomalies are encountered, relative to maintenance:
Hydraulic malfunction: droplet appearance on probe tip or bubbles in system.
Proceed as in section.
Message indicating replacement required.
Proceed as described on sections 0 to 0.
Insufficient cuvette drying or cleaning action.
Replace drying block. Perform wash unit maintenance.

8.6 Lamp replacement

When required, lamp replacement can be easily performed by user following these instructions:
Turn off and unplug instrument from Mains.
Remove lamp cover on left side of instrument, lamp will be visible.

! Do not touch lamp bulb. If touched accidentally, clean with lint-free cloth or tissue paper and alcohol.

1. Press lever on lamp socket to remove burnout lamp.
2. Insert new lamp in place securely. There is only one possible position due to different size of connecting pins.
3. Lamp is pre-focused, does not require other handling.
4. Reinstall cover, tighten screws.
5. Start instrument in the order mentioned in Daily Startup and Operation. Perform a calibration cycle. To do so, enter Movements menu and then select Calibrate.

8.7 Pump tube replacement

The pump tubing has a useful life given by a pre-fixed number of work cycles. When that number is surpassed, instrument will show a message for tubing replacement.
At the earliest opportunity the replacement must be done (it is not necessary to stop the automatic cycle).

1. Pull fittings up and out of bracket.
2. Pull tube out of its lodging rotating by hand the pump rotor if necessary.
3. Insert new tube on the fittings.
4. Install in inverse order.
5. Turn slowly rotor by hand until tubing is properly lodged.

Once replaced, proceed to reset cycle counter in

Maintenance > Operations > Wear

After replacement, select Paramters, then Cycles and press the reset button 0. This resets the counter; otherwise, the warning message will continue to be shown.

8.8 Dryer block replacement

Drying block should be replaced if symptoms of poor drying capacity are detected or when warning message is issued.
If cross-contamination is observed, first check if drying action is effective. Poor drying implies block change.
The drying block can be replaced by unscrewing it downwards until free, and inserting a new one in the pipe and screw it. Reinstall the washer head and rotate new block until it mates with cuvette shape.

If operation is difficult, remove the washer head by removing two screws that fix it, (see picture below) insert block and re-install wash head.

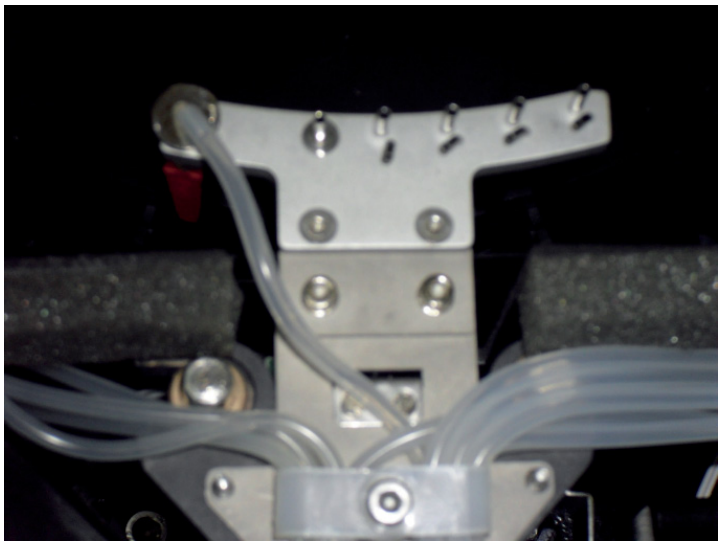


FIGURE 66

Once replaced, proceed to reset cycle counter in

Maintenance > Operations > Wear

8.9 Syringe replacement

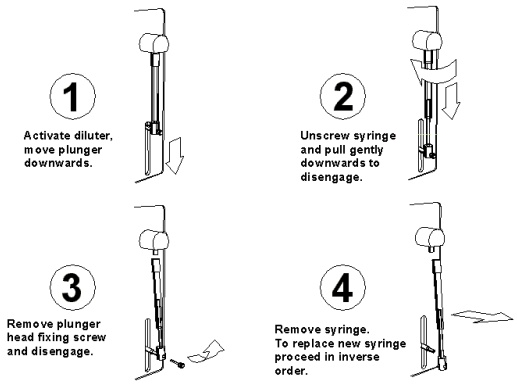
Instrument will warn when syringe cycles are close to its useful life, when it occurs, it is not necessary to replace it immediately, but at the earliest opportunity the replacement shall be done.
For replacement, syringe must be all the way down, as indicated in the figure.
Proceed to ***Maintenance > Operations > Movements***
Select in Diluter section, Fix, volume 500 microliters either back or front diluter and press hand or key F.

Once replaced, proceed to reset cycle counter in

Maintenance > Operations > Wear

And initialize by returning to the main menu and pressing the initialization button.

FIGURE 67



After replacement, select Parameters, then Cycles and press the reset button 0. This resets the counter; otherwise, the warning message will continue to be shown.

8.10 ISE Maintenance

8.10.1 ELECTRODE REMOVAL OR CLEANING

- Open small back door in rear panel of instrument with the aid of a screwdriver.
- Remove the fixing screw and flip the hinged ISE module out of the instrument.
- Loosen but do not remove two fixing hexagonal socket screws as shown in figure. They are located on the back side of ISE module.
- Move to the right the electrodes package so the electrode contacts are freed from the connecting clips.
- Pull electrodes down

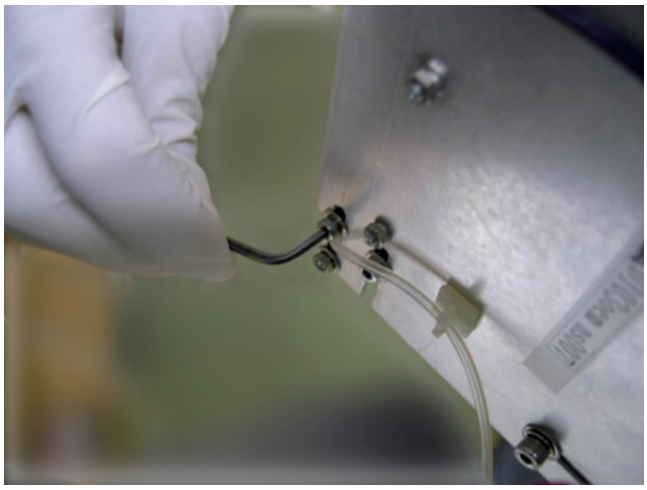


FIGURE 68

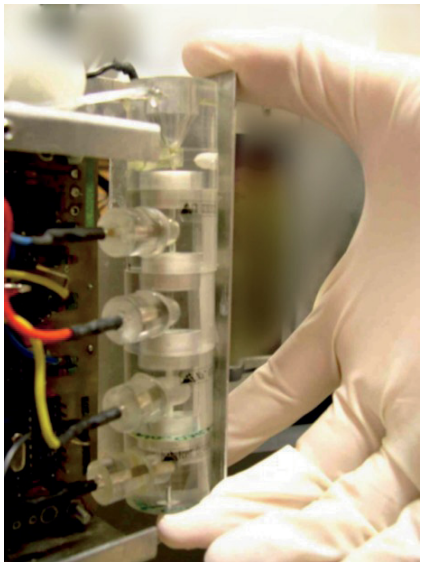
- Silicon rings between electrodes can be washed and re-used

FIGURE 69

- If necessary remove electrode and clean capillary tubing with cleaning solution. Rinse with distilled water.
- To re-install be sure to preserve the ordering: Cl, K, and Na from top to bottom. Press firmly the whole electrode package and re-adjust screws on the back.

- Push the electrode frame to the right so electrode contacts are hold by clips.

FIGURE 70



8.11 Pinch valve unclogging

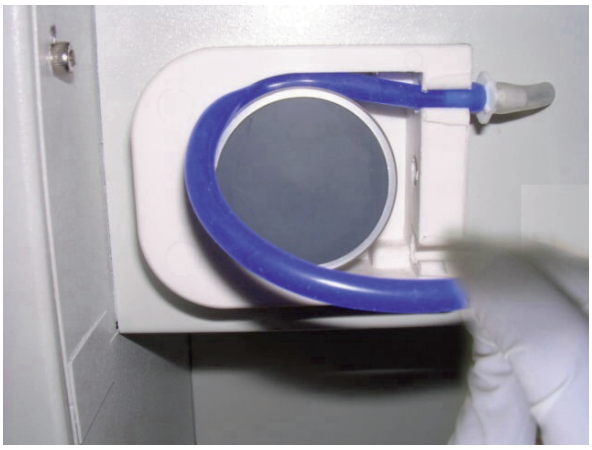
FIGURE 71

- Pull tubing as indicated by arrow in picture.
- Press corresponding Standard button at the same time. (***Maintenance > Operations > ISE***)
- Once outside valve, rub with fingers until standard flows normally.
- Re-install in pinch valve by pushing tubing and pressing delivery standard button at the same time.
- Perform procedure for valves A and B.

8.11.1 PUMP TUBING REPLACEMENT

- Open lower compartment in the rear panel where ISE pack and peristaltic pump are located.
- Rotate peristaltic pump tubing rotor and gently pull tubing end as shown.
- Remove connectors.
- Re-install new tubing. Be sure that connecting tubing has no kinks. Pass them through holes, if necessary
- Do not forget to reset the ***ISE number of samples,*** as indicated in 8.1..

FIGURE 72



8.11.2 ELECTRODE RECOVERY

Sometimes, mainly after measuring many consecutive urine samples or if cleaning procedure is repeated several times, slopes might decrease to values well below the stability threshold (30). Before any attempt to replace electrodes, load system with any serum sample and leave it in contact with electrodes for about 30 minutes. Next, empty module and calibrate.

Complete procedure should be as follows:

- Select ***Maintenance > Operations > ISE***
- In ***Electrode conditioning*** section, select the number of minutes for electrode conditioning. Conditioning could range from 30 minutes to several hours.
- Press ***Start*** button.
- System will prompt for placement of conditioning serum in the primer position.
- Once accepted the priming serum will be delivered and loaded in the ISE module and ending time shown in the screen.
- Only ISE module will remain inactive: all the other instrument sections and activities remain alive.
- When conditioning ends, repeat calibration procedure. Repeat conditioning, if necessary.

8.11.3 SODIUM ELECTRODE CONDITIONING

When Na^+ calibration slope slips down (below 30), Na^+ instability or more than 15 days elapsed since treatment messages are displayed, a conditioning cycle is recommended, Use

Maintenance > Operation > ISE

And press ***Na conditioning*** button.

ISE Na conditioner solution is a **Fixed** solution. It can be defined in any tray position.

9 TROUBLESHOOTING

Instrument related problems can be classified into three groups:

1. Operation malfunctions with visual, acoustic or printed warnings.
2. Visible faults or problems.
3. Measurement inconsistencies (for example: GOT method with high dispersion).

9.1 Messages and Warnings

Self-explanatory messages are not included in the present listing.

TABLE 18

Message	Cause	Action
Change reaction cuvettes.	All 80 cuvettes are dirty.	Replace reaction cuvettes.
Front / Back syringe exceeded.	Preset limit is surpassed.	Replace at the earliest opportunity. Follow procedure outlined in Section 8.9..
Front / Back pump turns exceeded	Preset limit is surpassed.	Replace at the earliest opportunity. Follow procedure outlined in Section 8.9..
There is no enough cleaning solution.	Cleaning or rinsing solutions are missing.	Replace required wash solution.

9.2 Visible faults

9.2.1 GENERAL FAULTS

TABLE 19

Symptom	Corrective Action
Drops on probe tip after dispensing	Verify hydraulic system in accordance to user's manual. Clean probe tip by submerging in Solution 1 for 5 minutes.
Drops on tip after wash cycle.	Verify hydraulic system for leaks or obstructions.
Abnormal noises.	Defective fans. Moving parts blocked or frozen. Contact Technical Support.

Temperature in reaction tray is too high. (Do not be concerned about arm probe temperature)	Room temperature too high, (should always be at least 4°C lower than selected working temperature). Example: For 37°C incubation temperature, Room temperature should not exceed 33°C. If Room temperature is within limits, and problem persists, call Technical Support.
Temperature in reaction tray is too low. (Do not be concerned about arm probe temperature)	Room temperature excessively low. Verify instrument operating range, and adequate the room temperature. If room temperature is within specified range and problem persists, call Technical Support.

9.2.2 AUTOMATIC CUVETTE WASHER MALFUNCTIONING

TABLE 20

Symptom	Corrective Action
At the end of wash cycle, tiny water droplets remain on cuvette walls	Verify that all pumps are working. Verify that no tubing are clogged Replace drying block Calibrate washer unit position.
High cross-contamination	Identify cross-contaminants and set methods in the Table of interferences Increase the wash volume Increase the number of wash cycles

9.2.3 MEASUREMENT INCONSISTENCIES

Consider storage and handling of reagents, standards and controls:

1. Verify expiration date, storage temperatures on and off analyzer.
2. Check that reagent was not frozen. Check color changes, sediments, turbidity, no foam.
3. Check for mixed reagents from different lots or re-use of reagent bottles.

All methods

1. Verify cuvettes for dirt or scratching.
2. Remove cuvettes from reaction tray and check volumes for affected cuvettes.
3. Verify there are no bubbles or droplet.
4. Verify there are no obstructions on probe, check for non constant or regular flow.
5. Recalibrate photometer.
6. Perform energy, noise and photometric stability tests.

Colorimetrics with high dispersion

1. Replace sample by a standard and verify dispersion again, check reaction cuvette-beam alignment.
2. Perform hydraulic verification.
3. Check for sample centrifugation, increase time and speed.
4. Perform energy, noise photometric stability and dilution tests.

Colorimetrics with proper dispersion but values too high or low

1. Verify standard, compare calculated factor with stored (historic) factors, and recalibrate method. If problem persists, replace standard and/or reagent.
2. Clean probe and check for cross contamination by changing the order of dispensing ("Time priority for reagents" parameter). Check proper probe washing/clean probe.
3. Check for exceeded method linear range; compare method definition with reagent specification.
4. Verify sample volume is not excessive.
5. Perform stray light verification, high range and low range linearity test, and dilution test.

Kinetics with high dispersion or low linearity

1. Verify if incubation time is too short or heaters are not working properly.
2. Verify for abnormally high initial absorbance for decreasing kinetics (problems with reagent preparation) or too low on increasing kinetics. Replace reagents and compare results.
3. Check lamp for stability.
4. Use new cuvettes and test again, check cuvettes for dirt or scratching.
5. Perform noise and photometric stability tests, clean filters.
6. For some kinetics: verify if sample volume is too low.
7. For some kinetics: verify centrifugation (increase time and speed).

Kinetics with normal values too high

1. Perform energy, noise and photometric stability.
2. Perform temperature verification.
3. Some kinetics: incorrect factor for selected temperature and volume.
4. Replace lamp, clean filters.

Kinetics with normal and pathological values too high

1. Verify incubation time and temperature. Perform temperature test.
2. Verify if factor matches selected temperature. Remember selected temperature is usually 37°C.

Kinetics with normal and pathological values too low

1. Check for short incubation time or low temperature.
2. Verify if factor matches selected temperature. Remember selected temperature is usually 37°C.

Kinetics with values too low or too high on the whole range

Verify if factor matches selected temperature. Remember selected temperature is usually 37°C.

Two point kinetics (high dispersion)

1. Verify if standard absorbance is too low (verify data provided by standard manufacturer).
2. Verify initial consumption is too high (verify data provided reagent manufacturer).
3. Perform energy tests.
4. Verify reagent handling and storage.
5. Check method parameter for reagent, low sample volume or too short interval times.
6. Check time table for dispersion on first measurement.

Two point kinetics (high dispersion)

Verify factor, standard and method for reagent.

Repetition or dilution (colorimetric or non linear kinetics)

1. Verify if sample volume is too high, check reagent linear limit.
2. Replace reagent and compare.

Repetition or dilution (two point kinetics)

This is not actually an error; it is because volume / absorbance change relationship is not linear, and so it is necessary to dilute standard and compare.

Reactions (general comparison between reactions)

1. Control quality of water.
2. Verify proper usage of solutions (wash solution, rinse solution, etc).
3. Use uric acid to check water quality.
4. Verify for frosted cuvettes (presence of salts).
5. Verify scratching or old reactions residues (not enough washing).
6. Perform instrument validation tests.

“Standard absorbance error” message

1. Check/replace standard.
2. Replace standard by a known concentration sample.
3. Decrease parameter “minimal standard absorbance”.

“Doubtful” flagged reaction

This message appears when concentration after dilution is lower than measured before dilution; it could be due a bubble, dirty probe or problem in reagent.

10 SYSTEM TESTS

To access to system tests, select 

Maintenance > System test

Results of tests are stored and printed out in PDF files in the Working Directory\System Tests.

10.1 Temperature

This test measures the time required for reaching preset temperatures and final stability of reading. It includes cooler tray temperature. The test records the minimum reached temperature and the last time in which the temperature reached the band between minimum and maximum allowed values. If the temperature is turned off, the test stops and a warning is issued.

10.2 Stray light

This test is based on the use of two solutions: one uv sharp blocking and other visible blocking.

Visible blocking is usually Potassium Chromate in high concentration (more than 5 g/l) and should block all light passing the cuvette at the specified wavelength. If it fails, light is arriving directly to sensor without traveling through the cuvette.

UV blocking, if visible is passed, indicates actual filter stray light. The use of Sodium Nitrite, 50 g/l and reading at 340 nm is recommended.

There are two options: either instrument dispenses solutions or user put them directly in the selected cuvettes. Use “Already dispensed” for selection.

Test is passed if read values are less than 0.1%T.

Volume selection can be used to determine minimum volume that can be safely measured.

10.3 Noise

This test determines the departure of individual readings from the mean value. Noise is evaluated separately from drift. For stability evaluation, total time (Number of readings X Time interval) should be at least 10 minutes. Noise evaluation is performed without moving tray and data are directly related to photometer behavior.

When Absorbance correction is selected (recommended for solutions and not for filters), results are expressed as equivalent to 1 cm cuvette measurements.
Noise test is relevant for absorbances over 1.300. Potassium Chromate (1.2 to 1.5 g/l in acidic media) is recommended.
Relevant data are peak-to-peak (maximum) difference. They should not exceed 0.002 for 1 minute total time.

10.4 Stability

Stability test is very similar to noise test, but the tray is randomly moving between readings. Comparison of data from noise and stability tests can give a hint on mechanical positioning problems. Use conditions as described in 10.3

10.5 Tip Pump

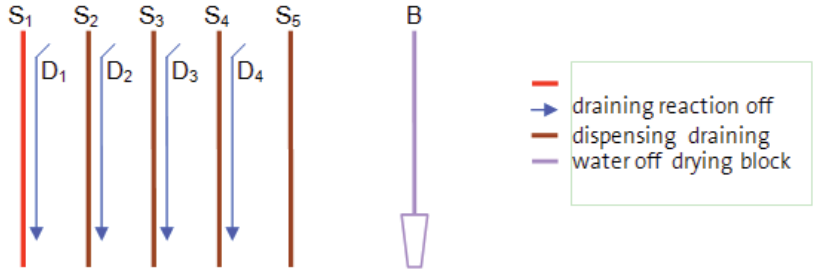
This test allows determining if washing tip pump is delivering the correct amount of water. Procedure is performed in a reagent bottle located in position 1, where initial liquid level should be at least to a height of 2 cm. Procedure is repeated several times and averaged.

10.6 Level detection

Reagent is taken from a vial located in a fixed position and tip reaches the surface of other reagent located in a different position. Next, reagent is delivered in the original one. This procedure is sequentially repeated while volume is varied every cycle within fixed limits. Results and plot will show if level detection is accurate. Use this test if detection problems are observed with a given method or Brand. When using, be sure that no foam is present in reagents or samples. If test is repeated many times, be sure that no foam is formed in the process.

10.7 Washer hydraulics

FIGURE 73



Calibration for cuvette bottom should be performed, prior to other operations.
A liquid pumping level check will be performed by dispensing water with D1 to D4 and measuring the liquid level with sensor probe (positions 2 to 5). The calculated volume will be recorded for each station (1 to 4).
A liquid suction level check will be performed drawing water with S1 to S5 and measuring the liquid level (if any) with sensor probe. To be able to measure such small remnant amount, the syringe full loaded with water (500 µL) will dispense 100 µL in each position (1 to 5). The calculated remnant volume will be recorded for each station (1 to 5).

A liquid pumping level stability test will be performed dispensing water with D1 to D4, the number of times determined by the parameter, in different cuvettes (positions 6 to 9, 10 to 13,) and measuring the liquid level with sensor probe. The following volumes will be recorded for each station (1 to 4):

- individual measurements;
- average volume;
- standard deviation and variance;
- minimum and maximum volumes;
- difference between minimum and maximum volumes;
- difference between minimum and maximum average volumes of the 4 stations;
- relative deviation error of average volumes.

A cuvette wash will be performed in all the used cuvettes.

10.8 Washer

Washer test consists of performing cuvette cleaning cycle on a programmed number of cuvettes. Absorbances are read on new cuvettes before cleaning action, immediately after cleaning and at some fixed time (Drying time). All three data are shown in the graph.
If cuvettes are properly dried and not scratched by the system, values should return to the original ones, with a tolerance of about 0.020 abs.

10.9 Dilution

Dilution test should be performed with a sample of Potassium Chromate of 5 g/l in acidic solution. Use as reagent the tip washing solution.
For a final volume of 4/400, CV should be less than 1.5%

10.10 Photometer linearity

This test is intended for evaluation of photometer linearity. To achieve this goal, the test will measure absorbance (A0 to A4) of 5 different solutions (points 0 to 4) in front and back channels using a specific filter. Each solution will be prepared by dilution of a stock solution located in a specific on-tray position. For a default initial sample volume of 8 microliters, system will automatically generate dilutions of 0/300, 8/292, 16/284, etc. maintaining the total solution volume unchanged.

A cuvette diluent blank will be performed prior to dispensing using a certain volume. Dilution will use the remaining volume of diluent. After dispensing, a certain time will be observed prior to reading. A certain number of replicates will be done for each point.
This test differs from 10.11 in the range of volumes. For volumes above 8 microliters, it is assumed that diluter linearity is out of question and any linearity departure is related to electronics or optics.

10.11 Diluter linearity

This test requires a concentrated Potassium Chromate solution (3 g/L in Perchloric acid 5 mmol/l) and washing solution as reagents. Given an initial volume (3 µL as default) system will generate dilutions using 1, 2, 3, 4 times the initial volume. Linear correlation and departure from linearity are evaluated. Departures of +/- 5% are accepted.

10.12 Level detection

Reagent is taken from a vial located in a fixed position and tip reaches the surface of other reagent located in a different position. Next, reagent is delivered in the original one. This procedure is sequentially repeated while volume is varied every cycle within fixed limits. Results and plot will show if level detection is accurate.
Use this test if detection problems are observed with a given method or Brand.

10.13 Chemistry analysis

Test allows selecting any method from any already defined Control Set and perform statistical analysis. Several analysis on methods belonging to the same control can be measured. Precisions are set default in 3% but operator should decide the required level.

10.14 Clot detector

Several determinations can be made over both detectors (front and back): Noise (dispersion), calibration and full measurement with real samples. The calibration determines a Factor (CF) and its value should be between 0,3 and 1,5.

Test can be performed with a sample or with water and a real reagent in tray. If the real used sample has high density or clot the test will fail, but this apparent failure is the verification of proper detector functioning, if the calibration is successful.

11 BACKGROUND

11.1 Methods types and calculation

Photometric methods can be split up into 3 categories as follows:

11.1.1 SINGLE POINT END POINT

11.1.1.1 Readings

A single absorbance reading (A_1) is taken at specified time after reagent addition. Other absorbance reading (Ae_1) may be taken immediately after the first reading for extra precision.

11.1.1.2 Measurement

$M = A_1 - B.$

where B is the measurement of the reagent blank if required, otherwise set to 0 The reagent blank determination is analogous to sample reaction.
If extra precision is required, measurement is computed as the average of the first and extra precision readings as

$M = ((A_1 + Ae_1) / 2) - B$

11.1.1.3 Limitations

Reagent times for R2/R3 (if any) shall be 0.

11.1.2 TWO POINT END POINT

11.1.2.1 Readings

The first absorbance reading (A1) is taken just before last reagent addition. The second absorbance reading (A2) is taken at specified time after last reagent addition.

11.1.2.2 Extra precision

Other absorbance readings (Ae1 and Ae2) may be taken immediately after each reading.

11.1.2.3 Measurement

The measurement is calculated as

M= (A2-F*A1) – B

Where F is a **Volume Factor Correction** given by

F= (V1 + Vs) / (V1 + V2 + Vs)
With V_1: first reagent volume
V_2: second reagent volume
V_s: sample volume

If no correction is applied, formula becomes

$M = (A_2 - A_1) - B.$

where B is the measurement of the reagent blank if required, otherwise set to 0.
The reagent blank determination is analogous to sample reaction.
If extra precision is required, readings are computed as the average of the first and extra precision readings as

$M = ((A_2 + Ae_2) / 2 - (A_1 + Ae_1) / 2) - B.$

11.1.2.4 Limitations

Reagent times for R2/R3 shall be greater than 0.

11.1.3 FIXED POINT

11.1.3.1 Readings

The first and second absorbance readings (A_1 and A_2) are taken at specified times (NT_1 and NT_2) after last reagent addition. Real reading times in seconds since last reagent addition are observed (RT_1 and RT_2).

11.1.3.2 Extra precision

Absorbance readings (Ae_1 and Ae_2) are taken 6 seconds before NT_1 and NT_2. Real reading times since last reagent addition are observed (RTe_1 and RTe_2).

11.1.3.3 Measurement

The measurement is calculated as

$M = ((A_2 - A_1) \bullet (NT_2 - NT_1) / (RT_2 - RT_1)) - B.$
where B is the measurement of the reagent blank if required, otherwise set to 0.
The reagent blank determination is analogous to sample reaction.
If extra precision is required, absorbance readings are interpolated from Ae_i at RTe_i and A_i at RT_i as

$$AI_i = Ae_i + (A_i - Ae_i) / (RT_i - RTe_i) \bullet (NT_i - RTe_i)$$

and measurement is calculated as

$$M = (AI_2 - AI_1) - B.$$

11.1.4 KINETICS

11.1.4.1 Readings

Absorbance readings (A_{c1} and A_{c2}) for rate evaluation (consumption) are taken at specified times (NT_{c1} and NT_{c2}, with values of 30 and 45 s) after last reagent addition. Real reading times in seconds since last reagent addition are observed (RT_{c1} and RT_{c2}).
Absorbance readings (A_1 to A_n) are taken at specified times (NT_1 to NTn, equally time spaced) after last reagent addition. Real reading times in seconds since last reagent addition are observed (RT_1 to RT_n). The number of readings is n = 10 in normal conditions.

Once the 10 readings are taken, the linear correlation coefficient is estimated; also, correlation is estimated but excluding all 10 points, one by one. System will select the condition of best correlation, excluding the worst point, if necessary.

11.1.4.2 Measurement

Consumption evaluation is calculated per 1 minute as

$$C = (A_{c2} - A_{c1}) / (RT_{c2} - RT_{c1}) \bullet (60\ s).$$

The measurement is calculated as

$$M = b(A_i, RT_i) \bullet (60\ s) - B$$

where B is the measurement of the reagent blank if required, otherwise set to 0.
The reagent blank determination is analogous to sample reaction.

With i from 1 to n, where b(y,x) function returns the slope of the linear correlation of absorbance against time pairs of values as shown in the following equation:

$$b = \frac{n\sum xy - \left(\sum x\right)\left(\sum y\right)}{n\sum x^2 - \left(\sum x\right)^2}$$

where x is the represents the time and y the absorbance.

12 APPENDIX

12.1 Technical Specification

TABLE 21

Throughput	450 tests/hour double reagent, 550 tests/tour mono reagent, max. 720 tests/ hour with optional ISE unit.
Analysis Modes	End point with sample or reagent blank. Factor or standard. Priority selection by sample (profile) or by reagent (batch). Calibration curve with any number of standards. Automatic curve fit, multipoint, logit 4/5, etc. Turbidimetry. Fast and two-point kinetics (zero and first order). Routine, batch, STAT procedures, profiles. Enzymes. Drugs. Automatic sample dilution on abnormal levels, excessive substrate consumption and/ or lack of linearity. Automated reflex testing. Full quality control: Levy-Jennings and Twin plots, Westgard rules. Import/export data, methods and historic files. Automatic backup procedure. Test selection, automatic calibration, calibration curve multipoint calibration, polygonal. Sample blank compensation, calculated tests, Quality control, auto re-run, record of calibration, data storage (historic results). Automatic pre-dilution and post-dilution (ratio 1:5 to 1:100) Stat: Highest priority in operation. Continuous sample load. Decontaminating post wash.
Sampling and reagent Samples	Sample volume: 2 to 100 µL/test (in increments of 0.2 µL. Sample Tray: 95 (5 racks x 19 positions) ID bar code equipped positions for routine, stat and control samples and standard solutions. Primary tube (length up to 100 mm), Pediatric vial
Reagents	Maximum number of simultaneous tests: 24 double to 48 single reagent tests + 3 with optional ISE unit. 1 to 3 reagents, 5 to 500 µL/test each (in increments of 1 µL), final total solution volume 180 to 500 µL/test Reagent bottles capacities: 20 and 70. Reagent cooling compartment: 48 cooled positions. Multiple vials per test. Reagent temperature 9°C+/-2°C for room temperature between 15 and 26°C.Above 26°C, 16°C+/-1°C below room temperature.

Reaction	Water consumption: 3 L / hour. Warm air incubator: 37°C. Reaction cuvette: re-usable plastic 6 mm light path with 6-stage washing Reaction time: 0 to 10 min. Reaction temperature: 37°C ± 0.1°C. Stirring: After dispensing each reagent.
Optics	Double beam Photometric Range: -0.1 to 3.6 A. Measuring wavelength: 340 to 800 nm (selectable among 12 wave-lengths). Photometry: Single or Double-wavelength simultaneous reading.
ISE Unit	Na^+, K^+ and Cl^- measurements. Samples: serum or urine.
Data Management	Windows™ based Software. Interface LIS: bi-directional RC 232 C, according to ASTM 1394 requirements.
Printout	Customer's optimized (Analysis result, work list, list of samples, Quality Control, Calibration curves, etc.)
Environmental conditions **Transportation and storage**	-10 to 40°C, humidity 30 to 90%, pressure 600 to 1050 hPa. Use: 15 to 30 °C, humidity 40 to 80%, pressure 600 to 1050 hPa.
Power Requirements	110/220V, 50/60 Hz, 2.0 kVA
Dimensions (WxDxH):	Instrument without any components: 100 x 74 x 113 cm Space required for routine use: 162 x 128 x 160 cm Packaging: 135 x 86 x 135 cm
Weight:	Gross: 250 kg, Net: 180 kg.

12.2 Calibration

Calibrations are intended for servicing trained personnel only. Log as service, then select:

Maintenance > Service > Calibration > Mechanical

And then the required section

12.2.1 MECHANICAL CALIBRATION

Initialize instrument.

12.2.1.1 Photometer

This calibration will determine the optimum reading position in the middle of each cuvette.

1. Select Front Tray, remove cuvette cover. Press F1 function or ***Start*** button
2. Use buttons or letters Q and E in keyboard until cuvette number 3 is close to photometer position. Use 10 steps or 1 step option as required. Photometer position is labeled with an arrow.
3. Close cover
4. Press ***Scan*** button. Instrument will scan cuvette number 3 and in Position window will write optimum calibration value.
5. Press F3 function or ***Confirm*** button.
6. Select Back Tray and repeat procedure.

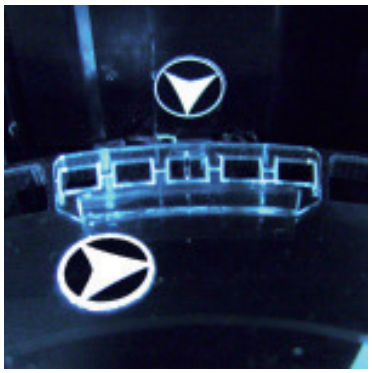


FIGURE 74

If instrument was already calibrated, ***Last*** button will position tray where last calibration was determined. This procedure will save time and item 3 can be skipped.
Once ***Start*** button is pressed, calibration can be aborted by pressing the ***Skip*** button.

12.2.1.2 Arm and Reaction Tray

This calibration will define that tip falls in the reaction tray in the middle of the reaction cuvette. Also, it defines the cuvette vertical position, which in turn, will define the dispensing height. Calibration includes positioning of cuvette washer module.

1. Select Front Tray; remove cuvette cover and cuvette retainer cover.
2. Press F1 function or ***Start*** button.
3. Use buttons or letters A and D in keyboard until tip is close to the center of cuvettes. Use 10-step or 1-step option as required.

4. Use buttons or letters W and S in keyboard until tip is few millimeters above cuvette.
5. Rotate tray by using buttons or letters Q and E in keyboard until cuvette number 1 (labeled with a sticker) coincides with tip position.
6. Repeat steps 3 and 5 until tip falls in the middle of cuvette number 1. For better sensitivity, use 1-step buttons. Do not fine tune vertical position at this time.
7. Press F5 function or ***Test*** button for verification and then F3 function or ***Confirm*** button.
8. Loosen washer head screws. Use buttons or letters R and F in keyboard until dryer block reaches cuvette bottom. Optimum setting is when block spring compresses about 1 mm. Use 10-step or 1-step option as required.
9. Tighten screws.
10. Press F5 function or ***Test*** button for verification and then F3 function or ***Confirm*** button.
11. Shift probe horizontally until tip is above cuvette body but outside cuvette itself.
12. Use buttons or letters W and S in keyboard and 1-step mode until tip just touches upper flat part of cuvette body.
13. Press F3 function or ***Confirm*** button.
14. Select Back Tray and repeat procedure.

FIGURE 75

! Last button does not act on vertical positions. This is so to prevent tip damage.

If instrument was already calibrated, ***Last*** button will position tray where last calibration was determined. This procedure will save time and item 3 can be skipped.
Once ***Start*** button is pressed, partial calibrations can be aborted by pressing the ***Skip*** button.

12.2.1.3 Washer

Use this window to calibrate the position when the drying block goes down to a cuvette.

1. Choose front washer, then press Start. Verify that drying block is in position 16.
2. Loosen calibrating screws. Use buttons or letters W and S in keyboard until drying block is completely in the cuvette and it slightly bents the reaction tray to ensure contact. Firmly adjust calibrating screws.

3. Use Last to position the block to the last available calibration.
4. Press Skip to cancel or Confirm to accept the calibration.

12.2.1.4 Arm and Washing Station

1. Select Front Tray.
2. Press F1 function or ***Start*** button.
3. Probe will approach to the washing station from the **left**. Use buttons or letters A and D in keyboard until tip is close to the center of washing station. Use 10-step or 1-step option as required.
4. Press F5 function or ***Test*** button for verification and then F3 function or ***Confirm*** button.
5. Use buttons or letters W and S in keyboard until tip just touches the bottom of station.
6. Press F3 function or ***Confirm*** button.
7. Press F5 the reaction (Test) function. Probe will go up, go to the reactive position and approach to the washing station from the **right** .
8. Use buttons or letters A and D in keyboard until tip position coincides with the center.
9. Press F5 function or ***Test*** button for verification and then F3 function or ***Confirm*** button.
10. Select Back Tray and repeat procedure.

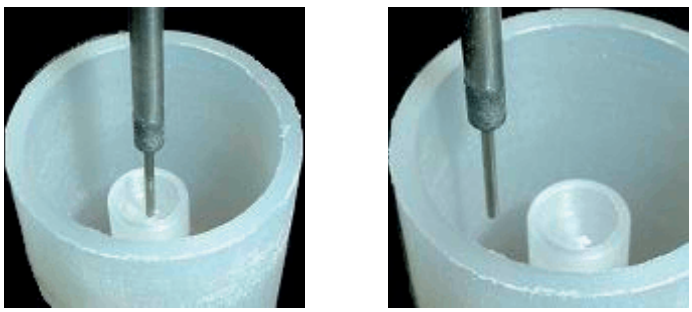


FIGURE 76

If instrument was already calibrated, ***Last*** button will position tray where last calibration was determined. This procedure will save time and item 3 can be skipped. Once ***Start*** button is pressed, partial calibrations can be aborted by pressing the ***Skip*** button.

12.2.1.5 Arm and sample Tray

1. Select Front Probe.
2. Press F1 function or ***Start*** button.
3. Use buttons or letters A and D in keyboard until tip is close to the center of **inner** sample ring. Use 10-step or 1-step option as required.

4. Rotate Sample tray by using buttons or keys Q and E in keyboard.
5. Repeat 3 and 4 until tip is in the center of sample **vial number 1**.
6. Press F5 function or ***Test*** button for verification and then F3 function or ***Confirm*** button.
7. Use buttons or letters W and S until tip just touches bottom of sample vial. Pull up frequently the vial while stepping down
8. Press F3 function or ***Confirm*** button. This will calibrate Primary Vial bottom (Standard 13 mm vial).
9. Use buttons or letters A and D in keyboard until tip is close to the center of ***Sample 2*** position. Use 10-step or 1-step option as required.
10. Rotate Sample tray by using buttons or keys Q and E in keyboard.
11. Repeat 3 and 4 until tip is in the center of sample ***vial number 2***.
12. Press F5 function or Test button for verification and then F3 function or ***Confirm*** button.
13. Use buttons or letters W and S until tip just touches bottom of sample vial. Pull up frequently the vial while stepping down
14. Press F3 function or ***Confirm*** button. If a different vial (pediatric) is used, Secondary bottom is calibrated, otherwise primary and secondary bottoms coincide.
15. Select Back Probe and repeat procedure.
16. ***Test*** button allows confirmation of settings

FIGURE 77

If instrument was already calibrated, ***Last*** button will position tray where last calibration was determined. This procedure will save time and items 3, 4, 9, and 10 can be skipped.

Once ***Start*** button is pressed, partial calibrations can be aborted by pressing the ***Skip*** button.

! Last button does not act on vertical positions. This is so to prevent tip damage

12.2.1.6 Arm and Reagent Tray

1. Fully remove the reagent cover.
2. Select Front Probe.
3. Press F1 function or ***Start*** button.
4. Use buttons or letters A and D in keyboard until tip is close to the center of cap of ***outer*** reagent ring. Use 10-step or 1-step option as required.
5. Rotate Reagent tray by using buttons or keys Q and E in keyboard.
6. Repeat 4 and 5 until tip is in the center of cap of reagent ***vial number 1***.
7. Use buttons or letters W and S until tip just touches cap of reagent vial.
8. Press F5 function or ***Test*** button for verification and then F3 function or ***Confirm*** button.
9. Use buttons or letters A and D in keyboard until tip is close to the center of **inner** reagent ring vial number 25. Use 10-step or 1-step option as required.
10. Rotate Reagent tray by using buttons or keys Q and E in keyboard.
11. Repeat 4 and 5 until tip is in the center of reagent **vial number 25**.
12. Press F3 function or ***Confirm*** button.
13. Repeat procedure for **vial 49** (physically located as the inner split vial on position 25).
14. Use buttons or letters W and S until tip just touches cap of reagent vial.
15. Press F5 function or ***Test*** button for verification and then F3 function or ***Confirm*** button.
16. Probe will position on reagent 1. Uncap reagent 1.
17. Use buttons or letters W and S until tip just touches the bottom of the vial.
18. Press F3 function or ***Confirm*** button.
19. Select Back Probe and repeat procedure.

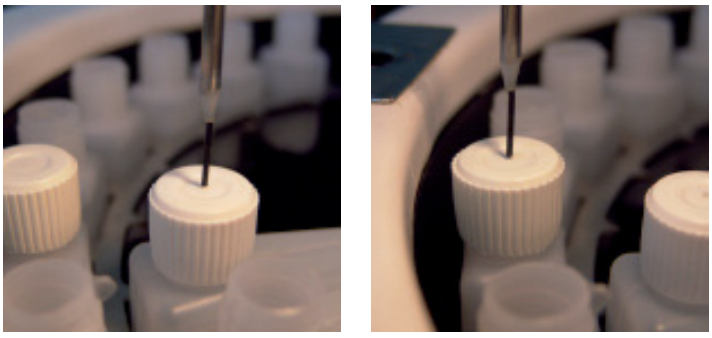


FIGURE 78

If instrument was already calibrated, ***Last*** button will position tray where last calibration was determined. This procedure will save time and one or more steps can be skipped.

Once ***Start*** button is pressed, partial calibrations can be aborted by pressing the ***Skip*** button. ***Test*** button allows confirmation of settings.

12.2.1.7 Sample Tray

This calibration is intended for alignment of sample sectors into the removal area.

1. Press F1 function or ***Start*** button.
2. Rotate Sample tray by using buttons or keys Q and E in keyboard until zone 1 is visible in the load area.
3. Re-adjust until sector can be loaded and unloaded through the loading area.
4. Press F3 function or ***Confirm*** button.

FIGURE 79

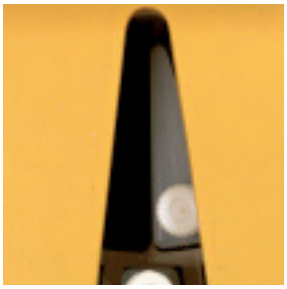
If instrument was already calibrated, ***Last*** button will position tray where last calibration was determined. This procedure will save time and item 1 can be skipped. Once ***Start*** button is pressed, calibration can be aborted by pressing the ***Skip*** button.

12.2.1.8 Reagent Tray

This calibration is intended for alignment of reagents into the removal area.

1. Press F1 function or ***Start*** button.
2. Rotate Reagent tray by using buttons or keys Q and E in keyboard until Reagents 1 and 25 are visible in the load area.
3. Re-adjust until reagents 1 and 25 can be loaded and unloaded through the loading area.
4. Press F3 function or ***Confirm*** button.

FIGURE 80



If instrument was already calibrated, ***Last*** button will position tray where last calibration was determined. This procedure will save time and item 1 can be skipped.
Once ***Start*** button is pressed, calibration can be aborted by pressing the ***Skip*** button.

12.2.1.9 Bar code Reader

1. Press F1 function or ***Start*** button.
2. Install in reagent 1 position a vial with valid bar code.
3. Use buttons or letters A and D in keyboard until vial is in front of BCR window. Use the 1-step option.
4. Press button or key R in keyboard and verify if code is read.
5. Repeat steps 3 and 4 until code is read. Look for the central position if code is read in a range of positions.
6. Press F3 function or ***Confirm*** button.
7. Repeat procedure for reagent located in position 25.
8. Install in sample 1 position a vial with valid bar code.
9. Use buttons or letters Q and E in keyboard until vial is in front of BCR window. Use the 1-step option.
10. Pres button or key R in keyboard and verify if code is read.
11. Repeat steps 3 and 4 until code is read. Look for the central position if code is read in a range of positions.
12. Press F3 function or ***Confirm*** button.

FIGURE 81

If instrument was already calibrated, ***Last*** button will position tray where last calibration was determined. Once ***Start*** button is pressed, partial calibrations can be aborted by pressing the ***Skip*** button.

12.2.1.10 ISE Modul

1. Press F1 function or ***Start*** button.
2. Use buttons or letters A and D in keyboard until tip is close to the center of ISE loading window. Use 10-step or 1-step option as required.
3. Press F3 function or ***Confirm*** button.
4. Use buttons or letters S and W in keyboard until tip touches the bottom of the loading cup. Use 10-step or 1-step option as required.
5. Press F3 function or ***Confirm*** button. System will automatically calculate the required steps up.
6. Use buttons or letters A and D in keyboard until tip is close to the center of ISE priming position. Use 10-step or 1-step option as required.
7. Press F3 function or ***Confirm*** button.
8. Use buttons or letters S and W in keyboard until tip is in the bottom of the ISE priming position. Use 10-step or 1-step option as required.
9. Press F3 function or ***Confirm*** button.

If instrument was already calibrated, ***Last*** button will position tray where last calibration was determined. This procedure will save time and item 2 can be skipped.

Once ***Start*** button is pressed, partial calibrations can be aborted by pressing the ***Skip*** button.

! ***Last*** **button does not act on vertical positions. This is so to prevent tip damage.**

12.2.2 PHOTOMETER CALIBRATION

Photometer calibration consist of automatic adjust of gains for front, back and reference channels. Also, energy ratios front/reference and back/reference are evaluated.

Ratios are used for absorbance calculations.

Calibrations must be performed only when lamp is changed or filters are cleaned or replaced.

Automatic Channel Ratio must be re-calculated about once every two weeks.

When calibration or ratio evaluation is started, the following message will be shown:

Place new cuvette in position 1

When calibration is performed, error messages will be issued if gains are too high or too low.

No conditions are established on ratios.

12.2.3 REAGENT BOTTLES

This calibration intends determining average area of bottle and bottom position, as seen from the front and back probes.
En each of four conditions, operator will be prompted to introduce the water volume (measured to the start of bottle neck) and introduce the bottle with a liquid level of about 5 mm from the bottom.

12.3 Barcode reader operation

12.3.1 DEFINITIONS

Closed system: An analyzer intended to be used with pre-filled, barcode-labeled reagent containers, to restrict operator's ability to use reagents obtained from sources other than the instrument's distributor.

Open Channel: It represents a reagent position reserved to allow an user defined assay in a closed system. This option provides some versatility by allowing a laboratory to purchase a reagent from a source different from the supplier, if required.

Open system: a system enabled to perform tests using reagents other than those supplied by the distributor of the analyzer.

12.3.2 USAGE OF BARCODE FEATURES

Samples
After pressing ***Place Sector*** for sector loading in the tray, all the sample barcodes will be read and the samples Id will be automatically loaded.
In case that the Auto Request test of LIS is enabled, instrument will automatically load all the required tests to be performed.

Sectors
When placing a sector, BCR will read the sector number from the barcode located on the sector.

Reagents

To request a reagent loading, open the reagent tray window, right click a suitable position, then choose ***change & BCR check***.

Press ***Apply Changes*** to start the loading process once all the requests are done.

12.3.3 PARAMETERS FOR BARCODE READER

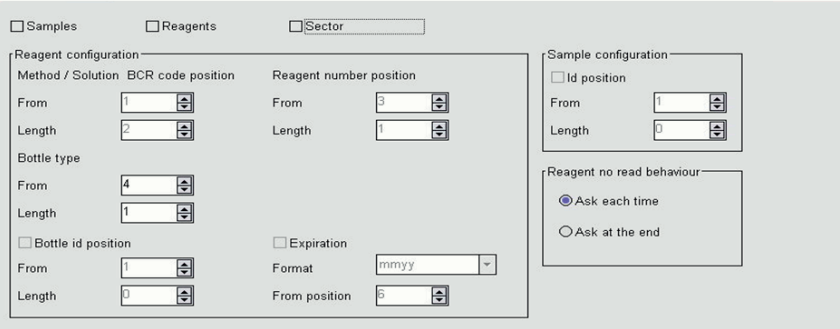
To access configuration, enter

Data > Log as supervisor

then press

Maintenance > Parameters > Software > BCR Tab

FIGURE 82



Tick on Samples, Reagents and Sector checkboxes to enable or disable the required features.

Sample configuration

Use Id position checkbox to enable the trim option for the barcode readings. Define origin (from) and length as required. (E.g. Setting from to two, means that the system will ignore the first letter of barcodes).

Reagent configuration (open system mode only)

For the definition of information contained in the barcode string, set origin (from) and length of each field. Do not overlap the fields.

Method / Solution BCR code: Code used as reference to identify a reagent or solution type.

Bottle type: Identifies the type of bottle, (1=small, 2=large, 3=split), see graph below.

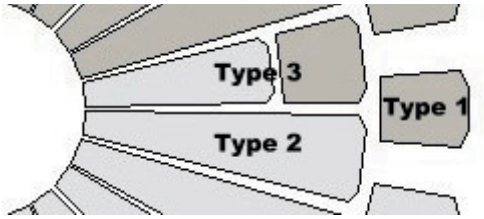


FIGURE 83

Reagent number: When using reagents having two or three components, this parameter represents the number of the component for the reagent.
For the case of a split bottle, given the outer reagent number, inner reagent number is a follows:

Outer	Inner
1	2
2	1
3	1

FIGURE 84

Bottle Id: Contains information related to the production or lot number.
Expiration: Sets date to alert when the reagent is expired.

12.3.4 IMPLEMENTATION OF BARCODES

Maximum length for samples and reagents barcodes, length is up to 20 alpha-numeric characters. For details on labeling position, see figure (Data expressed in mm).Available codes for both sample barcodes or reagent barcodes (on open systems), are Code 128 (NCCLS recommended), UPC/EAN, Code 39, PARAF, Tri-Optic, 2 of 5 Codes, Codabar, Code 93, Code 11, MSI Plessey and Telepen.

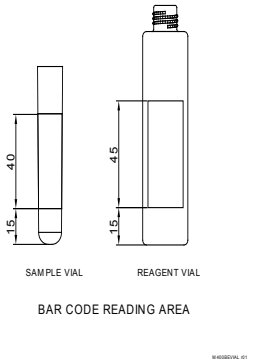


FIGURE 85

12.4 Service options

The following items belong only to Service manual and cannot be accessed by user.
They are protected with password. It should be introduced in

Data > Log as Service > Password

Once password is enabled follow:

Maintenance > Calibration

12.4.1 LAMP INTENSITY

When Start button is pressed, a continuous reading is shown in the screen: either *instantaneous* bar type plot or time evolution in a time/intensity plot.
Reading can be shown for any filter.
Use this option when re-adjust of lamp socket is required. In that case, maximize reading while getting both channels as equal as possible.
By using this option, filter wheel can be stopped and returned to normal mode.
This feature is only intended for testing purposes.
Time evolution allows determining if lamp intensity variations are responsible of stability problems.
Plot scales can be varied by clicking and dragging mouse on graph. If drag ends outside graph, axis returns to their original settings.

12.4.2 FILTER WHEEL

! Reading is slow; it takes approximately one second to refresh plot. Make small changes and wait for refreshed values.

Rotating filter wheel system requires fine adjustment of reading delays, filter by filter and for all channels.
This is a factory adjustment and it should not be modified unless a major servicing is required (motor replacement, sensor position adjustments, etc.)
Do not use if a filter is replaced.

1. Remove all cuvettes from light path.
2. Select to ***Reset delays*** to 20.
3. Keep normalization ***By channe***l
4. Press ***Start*** button.

5. Adjust offset until maximum for all channels and filters is approximately in the middle of the plot (10). This is a coarse adjustment.
6. Select ***Stay on filter***.
7. For fine tuning use the Delay buttons, filter by filter until all three channels are as centered as possible.
8. Press ***Stop*** button when done.

12.4.3 OTHER SERVICING OPTIONS

When service option is activated, other options are shown in

Maintenance > Service

12.4.3.1 Manual

When using Manual movements for testing purposes, be sure that parameter **Manual movements safety restrictions** in Debug section is activated, otherwise tip and other components could be damaged.

Whenever an order is issued, right side windows show low and high level communications.

When right clicking on a given communication line, Command Interpreter window is opened:

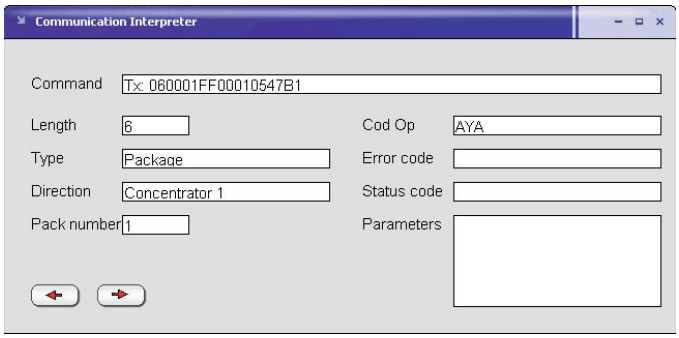


FIGURE 86

It displays description, direction, parameters, etc. which will help to debug errors related with it. Arrow buttons allow scrolling along the communication window.

12.4.3.2 Communication

This screen shows the level communications between instrument and PC.

Upper window shows high level communications, including request and answer.

Lower window shows the low level communications.

Window to the right shows Gantt diagrams. A Gantt chart is a graphical representation of the duration of tasks against the progression of time.
They depict dilution operations, including different modules and relative positions in a time scale.

12.4.3.3 Debug

This option allows instrument operation under limited conditions, enabling or disabling trays, probes, warning messages.
Particular care must be taken with option "**Manual movements safety restrictions**". Safety restrictions are those which put probe in a safe place before attempting movements. If disabled, tip and other parts are at risk.

! Parameters cannot be modified when instrument is in use.

12.4.3.4 Parameters

Filters. Wavelength definition of installed filters. There are 14 filter positions. Position 0 is always reserved to blocking (zero) filter and cannot be modified. For filter change, write in the right window new value and press button.
A zero value in wavelength for positions 1 to 14 means that the position is not used, regardless there is a filter or not.

Others.

Temperature

Front and back arms. Recommended range: 40°C to 43°C
Reaction Tray: 37°C to 39°C
Cool tray: 7°C (low) to 8°C (high) .

Pre and post-wash

Delivered volume with pumps when anti-interfering options are choosed
Recommended volume: 100
Recommended speed: 4320

Cuvette blank.

Limits and tolerance in the cuvette test. Tolerance refers to the allowed variation in each individual cuvette from the initial reading before being considered dirty.
Low limit (abs): 0.010
High limit (abs): 0.200
Tolerance (abs): 0.040

Pumps

Parameters which define the tip wash. They are valve opening times and are measured in milliseconds.
External wash: 750 milliseconds

System flush: 4750 milliseconds

Decompression: valve pre-opening time for pressure release purposes: 250 milliseconds.

Wear

Factory recommendation for warning on consumables expected life.

Each parameter, when surpassed, triggers a warning message.

The warning message presence does not prevent from instrument usage.

Washing station

Defines delivered water in cuvette wash stations. Water is delivered in four cuvettes at the same time, between 500 and 700 microliters in each one. So, total volume is between 2000 and 2800 microliters. Calibration is in step of peristaltic pumps.

Each pump turn corresponds to 400 steps.

ISE

Enables/Disables the option

Time pinch valves are open. Defines delivered volume of standards A and B. Its value must be adjusted to get a delivery of 180 µl.

ISE Thresholds

Define values in millivolts for detection of different fluids.

Instrument Serial Number

Stores instrument Serial Number

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